CE

VITEK 2™

Instrument User Manual

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Patent Information

Product covered by one or more of U.S. Patent Numbers D377,455; 5,670,375; 5,674,454; 5,697,409; 5,736,102; 5,762,873; 5,762,874; 5,798,084; 5,798,085; 5,853,666; 5,853,667; 5,856,193; 5,869,006; 5,881,781; 5,888,455; 5,891,396; 5,897,835; 5,925,884; 5,955,736; 5,965,090; 6,024,921; 6,086,824; 6,136,270; 6,156,565; D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890; 6,340,573; D397,611; D393,592; and Foreign Counterparts.

Warranty

Seller, bioMérieux, Inc., warrants the VITEK® 2 instrument (the "instrument") to the original purchaser for a period of one (1) year after date of installation against defects in material and workmanship and defects arising from failure to conform to specifications applicable on the date of installation. Seller further agrees to correct, either by repair, or, at its election, by replacement, any such defect found on examination to have occurred, under normal use and service, during such one (1) year period, provided Seller is promptly notified in writing upon discovery of such defect.

Seller shall not be liable under this Warranty for any defect arising from abuse of the system, failure to operate and maintain the system in accordance with the documentation included with the Instrument, including repair service, alteration or modification of the system by any person other than service personnel of bioMérieux, Inc., or Seller; or use of modified, changed, or previously used disposables.

The Warranty of Seller set forth above and the obligations and liabilities of Seller thereunder are exclusive and in lieu of all other remedies or warranties, express or implied, arising by law or otherwise, with respect to the system delivered hereunder (including without limitation any obligation of Seller with respect to merchantability, fitness for particular purpose, and consequential damages, and whether or not occasioned by Seller's negligence).

This Warranty shall not be extended or altered except by written instrument signed by Seller.

All of the product elements in the Seller's Instrument and the total instrument are warranted to be new or equivalent to new for the full product warranty period of one year. Disposables and replacement items with a normal life expectancy of less than one (1) year, such as batteries and bulbs, are excluded from this warranty.

STANDARD SYMBOLS

The following table presents symbols that may appear in the instructions for use or on the instrument, package inserts, or packaging.

	CE-Marking of Conformity
	Consult Instructions for Use
	Use by
	Manufacturer
	Date of manufacture
	Contains sufficient for <*n*> tests
	Keep dry
	Fragile, handle with care
	Caution, consult accompanying documents
	Biological risks

Electric shock warning

Radiation warning

Potential pinch-point warning

Laser

Temperature limitation

Upper limit of temperature

Lower limit of temperature

In Vitro Diagnostic Medical Device

Batch code

Authorized Representative in the European Community

Catalog number

Serial Number

Do not reuse

Recyclable

Separate collection for waste electrical and electronic equipment

Very toxic

Corrosive

Sodium azide

Irritant

Positive control

Negative control

Keep away from sunlight

Protect from light

This way up

Do not stack

Humidity limitation

Fuse

Direct current

Alternating current

Both direct and alternating current

Three-phase alternating current

Earth (ground) terminal

Protective conductor terminal

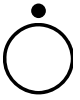
Frame or chassis terminal

Equipotentiality

ON (supply)

OFF (supply)

ON (only for a component of the system equipment)



OFF (only for a component of the system equipment)

Equipment protected throughout by double insulation or reinforced insulation (Equivalent to Class II of IEC 536)

GENERAL WARNINGS

IMPORTANT: ***The user is advised to read and understand all instructions in this manual to be able to derive the best performance from the VITEK® 2 instrument and the Smart Carrier Station.***

IMPORTANT: ***The configuration that you have purchased is adapted to the legislation and standards of the different countries it will be sent to. For this reason, it may differ from the one presented in this document. However, this will have no effect on the performance of your VITEK® 2 instrument or the Smart Carrier Station. For further information on peripherals (computer, printer, monitor, etc.) please refer to the relevant manufacturers' instruction manuals.***

IMPORTANT: ***If either the VITEK® 2 instrument or the Smart Carrier Station does not respond properly to keyboard inputs after an inadvertent electrostatic discharge or electrical fast transient, turn the power off, then back on using the power switch and resume normal operations.***

General Warnings

BIOHAZARD WARNING

This instrument may be involved with hazardous organism suspensions. This user manual does not purport to address all of the safety matters associated with the instrument's use. It is the responsibility of the user of this instrument to establish and follow appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.

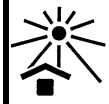
BIOHAZARD WARNING

All organism suspensions should be considered as potentially infectious. Qualified laboratory personnel should use acceptable procedures for biohazardous material.

LASER WARNING

All access doors and covers must remain closed when processing cards to avoid exposure to laser light.

AMBIENT LIGHT/DIRECT SUNLIGHT WARNING



The transmittance optics are sensitive to ambient light. Ensure all access doors are closed when cards are processing in the instrument. Do not place the instrument in direct sunlight. Strong light shining onto the front of the instrument can cause the optics to read incorrectly.

WARNING

This statement only applies to European countries with regard to the waste electrical and electronic equipment European directive:

You can play an important role in contributing to reuse, recycling and other forms of recovery of waste electrical and electronic equipment. Sorting this type of waste significantly reduces potential negative effects on the environment and human health as a result of the presence of hazardous substances in electrical and electronic equipment.

At the end of the life cycle of this product, do not dispose of the product as unsorted municipal waste, even if it is decontaminated. It is imperative that you contact bioMérieux to assure for its appropriate disposal.

Laser Caution

A laser caution label appears on the VITEK® 2 and VITEK® 2 XL at the following locations:

VITEK® 2	VITEK® 2 XL
• on the front access door	• on the left front access door
• on the inside panel behind the front access door	• above the center front sliding door
• behind the waste collection door	• behind the right side waste collection door

The label appears as shown here:

CAUTION
Laser light when open.
DO NOT STARE INTO BEAM.
530520-2

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How To Use This Manual 1

Introduction

This chapter gives you important information about how to use this manual. bioMérieux recommends that you read this chapter first.

IMPORTANT: ***Read this manual carefully before you attempt to operate the VITEK® 2 system.***

Chapter Contents

Organization • 1-2

Printed Documentation • 1-2

Intended Use • 1-2

How to Find Topics and Procedures • 1-3

Typographic and Usage Conventions • 1-3

References • 1-3

Graphical User Interface • 1-3

Warnings, Cautions, and Information • 1-5

Organization

The manual is separated into four basic parts:

- Part 1, which includes Chapter 2 and Chapter 3, covers the Smart Carrier Station. Chapter 2 describes the hardware and Chapter 3 provides the procedures you use to configure this station for your laboratory workflow.
- Part 2, which includes Chapter 4 and Chapter 5, covers the VITEK® 2 Instrument. Chapter 4 describes the hardware and Chapter 5 shows you how to configure the instrument's user interface.
- Part 3, including only Chapter 6, is the primary part of the manual. It describes all of the procedures you need to follow to process VITEK® 2 test cards. The chapter contains two subparts, one each to describe test card processing with, and without, a Smart Carrier Station.
- Part 4, consisting of Chapter 7 and Chapter 8, provides troubleshooting and maintenance procedures for the VITEK® 2 instrument.

Documentation

The documentation for the VITEK® 2 system consists of this manual and *VITEK® 2 Systems Product Information*. This division allows for the possibility that the computer workstation may be in a different location than the VITEK® 2 instrument and Smart Carrier Station.

- This manual covers the VITEK® 2 instrument and the Smart Carrier Station, including both the hardware and the programmed user interfaces.
- The *VITEK® 2 Systems Product Information* contains information about the test cards, including culture techniques, analytical techniques, and performance characteristics.

Intended Use

The VITEK® 2 and Smart Carrier Station (SCS) have applications as *in vitro* diagnostic medical devices.

How to Find Topics and Procedures

There are four tools to help you find a topic or procedure in the manual.

- **General Table of Contents.** This table is located in the front of the manual and includes the entire document. You can use this table to locate major headings throughout the manual. The table also includes a List of Tables and a List of Figures.
- **Chapter Table of Contents.** Each of the succeeding chapters begin with their own tables of contents. They contain the same information as the general table for the manual, but have the advantage of addressing only what is in that chapter.
- **Page Headers.** Each page in the manual has a header, which can serve as a visual aid to help you find a topic. The inside portion of the header, the side closest to the binding, always shows the chapter title. The outside portion of the header shows the title of the current section.
- **Index.** Found at the end of the manual, the Index is the most useful device for finding individual topics throughout the manual.

Typographic and Usage Conventions

References

References to chapter and section titles in this manual are in Proper Case.

Example: See Chapter 5, Configuring the VITEK® 2 Instrument.

References to other manuals are in Proper Case and italic font.

Example: See the *VITEK® 2 Systems Product Information.*

Graphical User Interface

Click

The term “click” refers to moving a mouse pointer to choose or select a command, window, button or option, then pressing the left, or primary, mouse button to initiate action in the software.

Example: Click **OK**

Commands

Menu, keyboard and button commands are in proper case, bold.

Example: **File > Quit** menu command

Names and Titles

The names and titles of menus, dialog boxes, fields, icons and toolbar buttons are in proper case, bold.

Example: **Setup** menu

The names of windows are in proper case, but are not bold.

Example: Configuration window

Press

The term “press” refers to holding down a key on the keyboard in order to initiate action in the software.

Example: Press **Enter**

Select

The word “select” is generally used for selecting menus, menu commands and GUI navigation.

Example: Select **File > Quit**

Screen Text

Text that appears on the screen will be shown in a monotype font.

Example: `Saline Test in Progress`

User Input

Instructions for user input begin with the word “type” or “enter.” These instructions use bold for literal user input and italic for placeholders.

Example of literal user input: Login as **micb**, and password **micb**

In this example, type exactly what you see on the page (micb in this example).

Example of a placeholder: Enter your *password* before you...

In this example, type your assigned password.

Warnings, Cautions, and Information

This manual uses different types of symbols to alert you to important information. Symbols and their associated information are labeled in text where they occur and set off from surrounding paragraphs, as shown in the following examples.

WARNING

Warning is a statement that alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of a device.

CAUTION: Caution is a statement that alerts the user to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, damage to the device, or damage to other property. Where applicable, a caution statement may include a precaution that should be taken to avoid the hazard.

IMPORTANT: ***Important relates to content presented in this manual. It is used to reinforce the importance of your understanding or remembering something.***

Note: *Note supplies additional information about a topic.*

SMART CARRIER STATION 2

Introduction

Use this chapter to familiarize yourself with the Smart Carrier hardware. It includes an overview of each part of the unit.

Chapter Contents

Purpose • 2-2
Unpacking Instructions • 2-2
Unpacking Procedure • 2-3
Installation Procedure • 2-4
Preparations for Operation • 2-5
Smart Carrier Station Overview • 2-6
SCS Keyboard • 2-8
SCS Base Unit • 2-9
System Physical and Electrical Requirements • 2-9
Setup Bar Codes • 2-10

Purpose

The purpose of this chapter is to aid in the safe handling, setup, configuration and operation of the Smart Carrier Station.

Unpacking Instructions

Figure 2-1 shows a Smart Carrier Station (SCS).

Figure 2-1: Smart Carrier Station

1 — Display Screen

2 — Power Supply

3 — Base Unit

4 — Bar Code Scanner

5 — Keyboard

Inspect the shipping container for external damage. If it has been damaged, inspect the SCS itself for damage. If the SCS has been damaged, file a claim with the shipper and notify bioMérieux, Inc.

Check the packing list included with the VITEK® 2 System and verify that all required items are included in the shipment.

Note: *The packaging materials and shipping container should be retained for future transportation needs, if necessary.*

WARNING

This statement only applies to European countries with regard to the waste electrical and electronic equipment European directive:

You can play an important role in contributing to reuse, recycling and other forms of recovery of waste electrical and electronic equipment. Sorting this type of waste significantly reduces potential negative effects on the environment and human health as a result of the presence of hazardous substances in electric and electronic equipment.

At the end of the life cycle of this product, do not dispose of the product as unsorted municipal waste, even if it is decontaminated. It is imperative that you contact bioMérieux to assure for it's proper disposal.

Unpacking Procedure

To remove the SCS from its shipping container:

1) Open the shipping carton and remove the unit from the carton.

2) Carefully remove the unit from the packing material. Be sure to remove all parts and literature from the carton.

3) Remove the remaining packing materials from the SCS and store with the shipping container.

WARNING

An electric shock hazard could exist if the enclosure of the SCS or its external power supply is damaged exposing electrical components.

Installation Procedure

After completing the unpacking procedure, the SCS is ready to be placed in its permanent location. The SCS is intended for use on any normal, flat bench top, commonly found in a microbiology lab, away from direct sunlight. Some cables must be connected to the unit. Figure 2-2 shows the cable connections on the back of the unit.

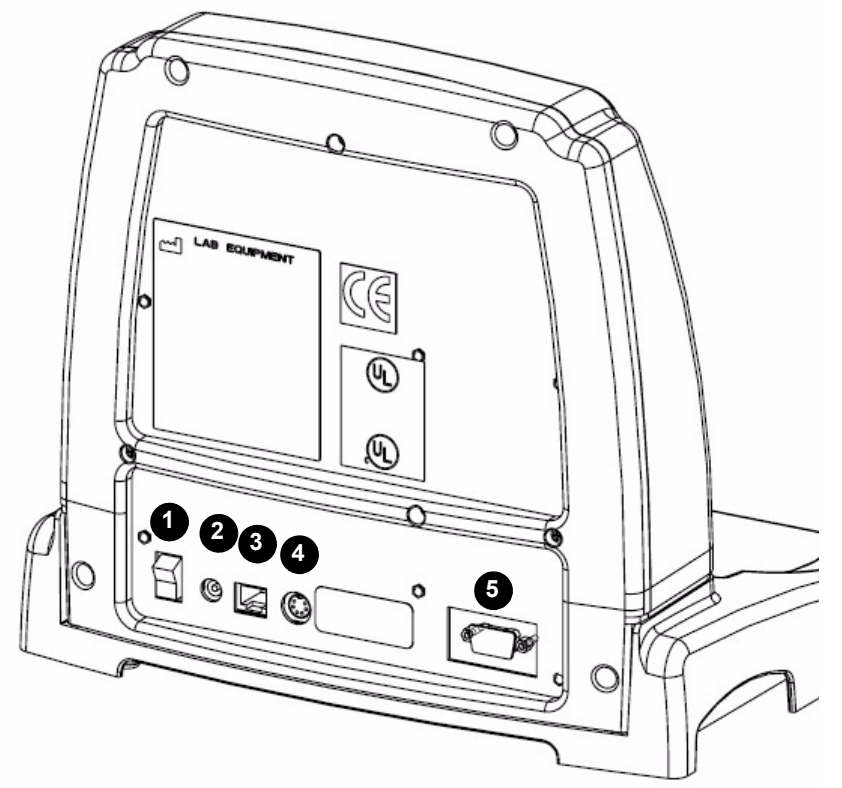


Figure 2-2: SCS – Cable Connections

The back panel of the base unit, shown in Figure 2-2, contains the on/off switch, the power cord receptacle, and the connector ports for various cables.

1 — On/Off Switch
2 — DC Power Receptacle
3 — Receptacle for the Bar Code Scanner
4 — Circular Connector for the SCS Keyboard
5 — Service/Update Cable Connector

Preparations for Operation

Place the SCS in its permanent location.

WARNING

Do not place the SCS in a location where it could be exposed to direct sunlight during operation.

Position the instrument to meet the minimum clearance of 5 cm (2 in.) on all sides and 30.5 cm (12 in.) above the instrument to provide adequate space for placing cassettes onto the unit.

Use this procedure to begin using the SCS. The unit should be located on a bench top with room next to it for test cards and specimens. Use Figure 2-2 of the SCS to locate and identify the various parts referred to in the procedure.

WARNING

An electric shock hazard could exist if the SCS or its external power supply is immersed in water.

1) Connect the SCS keyboard to its receptacle (**4**, Figure 2-2) on the back of the base unit.

2) Connect the bar code scanner to its receptacle (**3**) on the back of the base unit.

3) Connect the external power supply cord to the back of the SCS (**2**) and the main cord to an AC power outlet.

4) Push the **On/Off** switch (**1**) to turn the unit on. The computer takes a few moments to go through its startup routine.

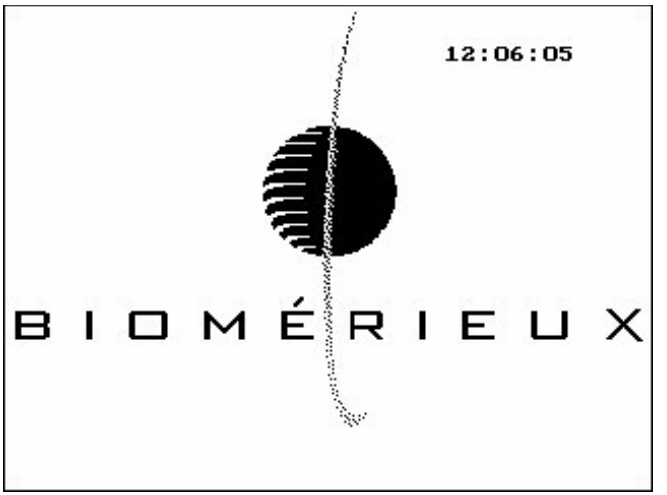


Figure 2-3: Initial SCS Screen

5) When the SCS is ready to be used, the screen shown in Figure 2-3 will be displayed. If there is no display, switch the power OFF and restart at Step 2.

Note: *If you have not yet customized your configuration settings, the Configuration screen is displayed. For information on changing the settings, see Chapter 3 in this Manual.*

Smart Carrier Station Overview

The Smart Carrier Station (SCS) is a small computer dedicated to collecting information about test cards and specimens, and for transferring that information to the VITEK® 2 instrument. The SCS, shown in Figure 2-4, has five main components.

Figure 2-4: The Smart Carrier Station

1 — SCS Base Unit. The SCS base contains the microprocessor. There are connection ports on the back of the base for the keyboard and the bar code scanner. The top of the base is specifically shaped to accept a cassette. Metal contacts on the base connect the unit's computer to a button memory chip on the cassette. Ensure that the cassette is fully seated in order to make an electrical connection to the cassette memory. This memory chip stores the information you entered to be transferred to the workstation.

2 — SCS Display Screen. The display for the SCS is a liquid crystal display (LCD). Use the display to view and confirm the information you are entering for the test cards and specimens.

3 — SCS Bar Code Scanner. The SCS is equipped with a bar code scanner that allows you to enter data with a simple bar code scan rather than repeated typing. You can scan most data fields. The data appears automatically on the display. The scanner can be hand-held or used while mounted in its holder.

4 — SCS Keyboard. The SCS keyboard has a standard set of alphanumeric keys, plus several specially designed keys for SCS functions. The SCS

keyboard is smaller than a standard size keyboard, so it can be stored under the Base Unit.

5 — External Power Supply. The SCS is powered by an external DC power supply. This power supply accepts 120 VAC to 240 VAC mains power via a detachable two conductor power cord.

SCS Keyboard

The SCS keyboard has a standard set of alphabetic and numeric keys. It also has several keys that are uniquely designed for use on the SCS.

Figure 2-5: The SCS Keyboard

Help. Displays context-sensitive help screens and data field option boxes.

Previous Slot/ Next Slot. This key has two functions. When you press the arrow on the left, the display changes to the **Previous Slot.** When you press the arrow on the right, the display changes to the **Next Slot.**

Shift. Changes case of letter entered on keyboard.

Shift Lock. When **Shift Lock** is selected, the light next to the shift lock key goes on and the keypad stays in the upper case mode. Press **Shift Lock** again to cancel upper case mode.

SCS Base Unit

The base unit for the SCS contains the electronic components that make its data entry and storage functions possible. The power switch and cable connectors are located on the back panel of the base unit.

The base unit is actually a small computer with its own processing unit, memory, and software program. However, the program in this computer is limited to the task of entering and storing data for a cassette.

System Physical and Electrical Requirements

These physical specifications do not include the bar code scanner or the external power supply.

Table 2-1: Physical Characteristics

Height:	27.6 cm (10.9 in.)
Width:	30.5 cm (12.0 in.)
Depth:	23.2 cm (9.1 in.)

Table 2-2: Electrical Requirements

Input Voltages/ Currents:	100/120 VAC +/- 10% (auto range) at 0.22 amp nominal 200/240 VAC +/- 10% (auto range) at 0.11 amp nominal 50/60 Hz
Power:	27 watt (nominal)
Heat:	92 BTU/Hr (nominal)
Power Cord:	Detachable 2 wire with an IEC 320 C7 appliance connector

Table 2-3: Environmental Requirements

Indoor Usage	
Do not install in direct sunlight.	
Pollution Degree 2 in accordance with IEC 664	
Over voltage Category II per IEC 664	
Ambient Room Temperature:	15 ºC to 30 ºC

Table 2-3: Environmental Requirements (Continued)

Shipment and Storage Temperature:	–20 ºC to +50 ºC
Humidity:	20% to 80% (Non-Condensing)
Minimum installation altitude:	–100m
Maximum installation altitude:	2000m

WARNING

Do not operate the SCS in an environment above 30 °C (86 °F)

Setup Bar Codes

The bar code scanner is programmed at the factory. Use these setup bar codes in the event that the Bar Code Scanner loses its settings.

1) Press **F4** to access the Configuration screen.

2) Press **Next** or **Previous Screen** until the Firmware Update screen displays.

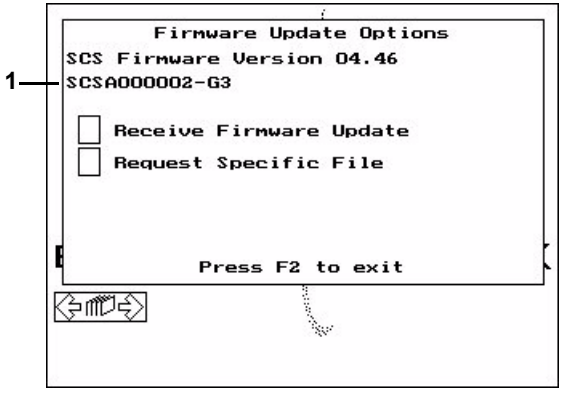


Figure 2-6: SCS Firmware Update Screen

3) Review the last two digits of the serial number (**1**, Figure 2-6) to determine which generation of SCS is in use.

4) Press **F2** to exit the Configuration screen.

5) Refer to Table 2-4 and print the applicable bar code figure to use to program the bar code scanner.

IMPORTANT: ***Print the applicable bar code figure using a laser printer.***

6) Align the scanner several inches away from the first bar code illustrated in the applicable figure.

7) Pull the trigger on the scanner and align the red beam over the bar code. When the scanner emits a two-toned beep, release the trigger.

8) Align the scanner several inches away from the next bar code illustrated in the applicable figure.

9) Pull the trigger on the scanner and align the red beam over the bar code. When the scanner emits a two-toned beep, release the trigger.

10) Repeat Step 8 and Step 9 until all bar codes in the figure have been scanned.

Note: *The bar codes are numbered in the order they should be scanned.*

The scanner is now programmed.

For more information on the configuration and operation of the Smart Carrier Station and Bar Code Scanner (including configuration for 'stand' and 'hand held' modes) refer to the instructions provided with the scanner stand (included with the Smart Carrier Station) and Chapter 3, SCS Configuration.

Table 2-4: Bar Code Scanner Model References

SCS Common Name	SCS Part Number(s)	Bar Code Reader	Bar Code Reference Figure
1st Generation or G1	530001-1 530001-2	Model 3400 (Scanner ID Number 722106) P/N 531130-1 (Discontinued)	Figure 2-7
		Model 3800 (Scanner ID Number IT3800) (Programmed to XT Mode) P/N 514144-1	Figure 2-9

Table 2-4: Bar Code Scanner Model References (Continued)

SCS Common Name	SCS Part Number(s)	Bar Code Reader	Bar Code Reference Figure
2nd Generation or G2	530001-3 530001-4 27203 27204	Model 3400 (Scanner ID Number 722106) P/N 531130-1 (Discontinued)	Figure 2-8
		Model 3800 (Scanner ID Number IT3800) (Programmed to AT Mode) P/N 514144-2	Figure 2-10
3rd Generation or G3	27209	Model 3800 – Black	Figure 2-10

1 Factory Default

2 PC-XT Format

3 Enter Program Mode

4 Set Inter char delay

5 Code 0 (3-27)

6 Code 2 (3-27)

7 Exit PGM mode

8 Enter Program Mode

9 Good Read Delay

10 High

11 Exit PGM mode

Figure 2-7: Bar Codes for Bar Code Scanner – A

1 Factory Default

2 PC-AT Format

3 Enter Program Mode

4 Set Inter char delay

5 Code 0 (3-27)

6 Code 2 (3-27)

7 Exit PGM mode

8 Enter Program Mode

9 Good Read Delay

10 High

11 Exit PGM mode

Figure 2-8: Bar Codes for Bar Code Scanner – B

Factory Defaults

1

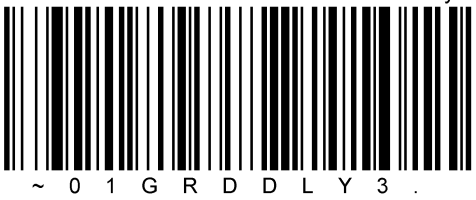
IBM/XT Interface CR Suffix

2

Intercharacter Delay 10ms (02) Good Read Medium Delay

3

Interscan delay



4

Figure 2-9: Bar Codes for Bar Code Scanner – C

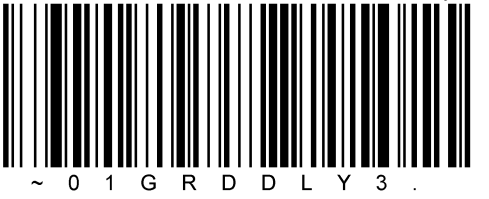
Factory Defaults (AT Interface)

1

CR Suffix Intercharacter Delay 10ms

2

Interscan delay



3

Figure 2-10: Bar Codes for Bar Code Scanner – D

SCS CONFIGURATION 3

Introduction

Configuration options allow you to operate the Smart Carrier Station in a number of different ways. This chapter explains not only how to set these options, but also how each option affects the data stored in the button memory of a cassette.

Chapter Contents

Configuration Overview • 3-2

When to Configure • 3-2

Accessing Configuration Screens • 3-3

SCS Main Configuration Options • 3-3

Cassette ID • 3-3

Setup Technologist ID • 3-4

Bench Name • 3-4

SCS Workflow Configuration Options • 3-5

AST Dilution Mode • 3-5

Erase Cassette • 3-6

Begin Data Entry • 3-6

SCS Utilities • 3-7

Language • 3-7

Audible Feedback • 3-8

Host Type • 3-8

Time and Date • 3-8

SCS Firmware Update • 3-9

Configuration Overview

When to Configure

Set SCS configuration options before you insert a cassette and enter information for the test cards. When first turned on, the Configuration Screen is displayed if you have not customized your settings.

Note: *One exception to this is the **Firmware Update** screen. You do not need to use that screen until you receive instructions from bioMérieux to do so.*

There are eleven configuration options on the SCS:

Table 3-1: SCS Configuration Options

Configuration Screen Name	Option	Reference
Smart Carrier Station Configuration	Cassette ID	page 3-3
	*Setup Technologist ID	page 3-4
	*Bench Name	page 3-4
Workflow Configuration	AST Dilution Mode	page 3-5
	Erase Cassette	page 3-6
	Begin Data Entry	page 3-6
Utilities	Language	page 3-7
	Audible Settings	page 3-8
	Host Type	page 3-8
	Time and Date	page 3-8
Firmware Update	Firmware Updates	page 3-9

*This field will be displayed and available only if the Host Type field is set to “PC”.

The options are divided among four screens:

- **Smart Carrier Station Configuration –** Includes the Cassette ID, Setup Technologist ID, and Bench Name options.
- **Workflow Configuration –** Includes the AST Dilution Mode option, the option for automatically erasing the cassette memory, and an option for determining the start point of the Cassette Edit screen.
- **Utilities** – Includes the Language, Audible Feedback Settings, Host Type, and Time and Date options.

- **Firmware Updates –** Displays the current firmware version and includes options for uploading new software for the SCS.

Accessing Configuration Screens

Access the SCS Configuration screen by pressing **F4**, followed by the **Previous** or **Next Slot** key to switch to the other screens.

SCS Main Configuration Options

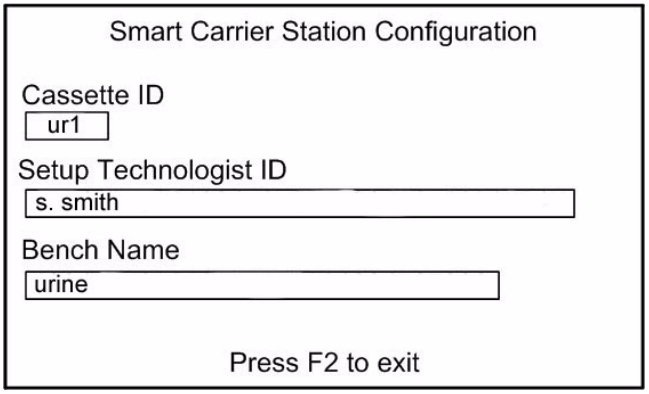


Figure 3-1: SCS Main Configuration Screen

Cassette ID

When test information is entered into a Smart Carrier Station, the Cassette ID is also saved to identify the cards that were processed in that cassette. This is especially useful in laboratories with multiple Smart Carrier stations.

The Cassette ID consists of one to three alphanumeric characters. An SCS name may reflect something about the use of the station. If, for example, a particular individual is assigned to an SCS, that individual's initials can be used for the SCS name. The Cassette ID becomes a part of each test card's address that appears on the workstation's card directory.

Note: *The Cassette ID field cannot be blank. If you do not enter a custom value in the Cassette ID field, the default Cassette ID of "SCS" will be used.*

Note: *Single digit numerals are reserved for use with the VITEK® 2 PC Virtual Cassette workflow and are not allowed for use as a Cassette ID by the SCS.*

Setting Cassette ID

1) Press **F4** to access the Configuration screen.
2) In the **Cassette ID** field, type up to three *characters* and press **Enter**.
3) Press **F2** to exit the SCS Configuration screen.

   or

   Press **Next** or **Previous Screen** to access other configuration screens.

Setup Technologist ID

The Setup Technologist ID field allows you to enter your name at the SCS and transfers that information to the workstation. This field will be displayed and available only if the Host Type field is set to “PC”.

Setting Setup Technologist ID

1) Press **F4** to access the Configuration screen.
2) Press the **Down Arrow** key to move the cursor to the **Setup Technologist ID** field.
3) In the **Setup Technologist ID** field, type up to thirty-five *characters* and press **Enter**.
4) Press **F2** to exit the SCS Configuration screen.

   or

   Press **Next** or **Previous Screen** to access other configuration screens.

Bench Name

The Bench Name field allows you to enter an alphanumeric name that tags a bench (or Sample Area) where a given cassette was set up. This field will be displayed and available only if the Host Type field is set to “PC”.

Setting Bench Name

1) Press **F4** to access the Configuration screen.
2) Press the **Down Arrow** key to move the cursor to the **Bench Name** field.
3) In the **Bench Name** field, type up to thirty *characters* and press **Enter**.
4) Press **F2** to exit the SCS Configuration screen.

   or

   Press **Next** or **Previous Screen** to access other configuration screens.

SCS Workflow Configuration Options

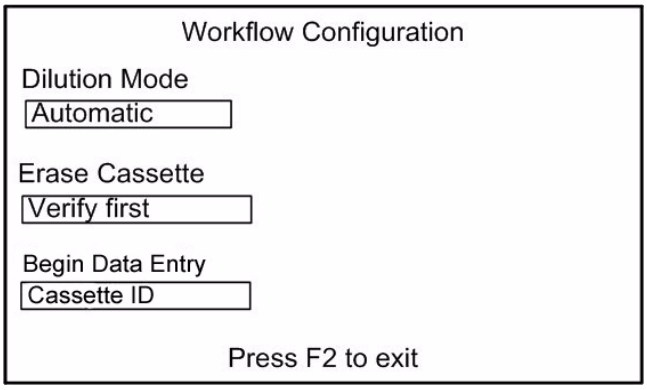


Figure 3-2: SCS Workflow Configuration Screen

AST Dilution Mode

An AST, or Antimicrobial Susceptibility Test, uses an inoculum that is specifically diluted according to the type of test card being used. These inocula can be prepared manually by the technologist, or prepared automatically by VITEK® 2 at the Dispenser/Pipettor station.

The AST Dilution mode setting is transferred to the VITEK® 2 instrument using the cassette memory. If you set the AST Dilution Mode to automatic, every AST in a cassette has its inoculum diluted by VITEK® 2. If the AST Dilution Mode is set to pre-diluted, VITEK® 2 assumes that the AST dilutions have already been performed.

Setting AST Dilution Mode

1) Press **F4** to access the Configuration screen.

2) Press **Next** or **Previous Screen** to access the Workflow Configuration screen.

3) Press **1** to set the dilution mode to Automatic (default).

or

Press **2** to set the dilution mode to Pre-diluted (manual).

4) Press **F2** to exit the SCS Configuration screen.

or

Press **Next** or **Previous Screen** to access other configuration screens.

Erase Cassette

The Cassette Erase function gives you the option of automatically erasing cassettes that have been processed by the VITEK® 2 instrument.

Setting Cassette Erase

1) Press **F4** to access the Configuration screen.

2) Press **Next** or **Previous Screen** to access the Workflow Configuration screen.

There are two settings available, **Automatic** (default) and **Verify First.**

- Select **Automatic** to automatically erase cassettes that have been processed.
- Select **Verify First** to display and review data before it is erased.

3) Press **1** or **2** to select **Automatic** or **Verify First** as indicated on the screen.

Note: *If you select **Verify First**, when you place a cassette that has been processed by the instrument on the Smart Carrier Station, the following message displays:*

```
Cassette has been processed
```

4) Press **F1** to erase, or press any other key to display processed information.

5) Press **F2** to exit the screen.

Begin Data Entry

The Begin Data Entry function allows you to customize the workflow associated with the Cassette Edit screen.

Setting Begin Data Entry

1) Press **F4** to access the Configuration screen.

2) Press **Next** or **Previous Screen** to access the Workflow Configuration screen.

The possible settings are Cassette ID and Accession/Lab ID. (Accession ID is the same as Lab ID.)

- Select **Cassette ID** to begin data entry in the **Cassette ID** field of the Cassette Edit screen (default).
- Select **Accession ID** to begin data entry in the **Accession ID** field of the Cassette Edit screen.

3) Press **1** or **2** to select your preferred workflow as indicated on the screen.

4) Press **F2** to exit the Workflow Configuration screen.

or

Press **Next** or **Previous Screen** to access other configuration screens.

SCS Utilities

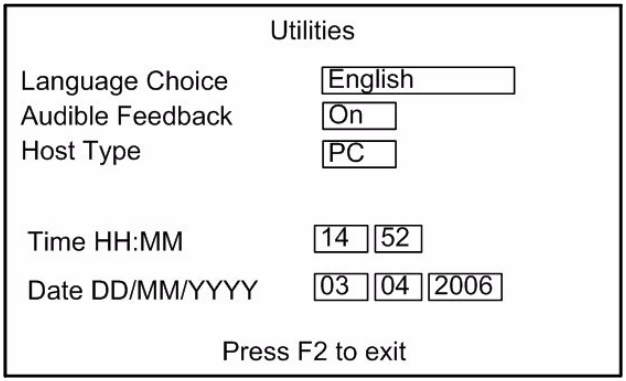


Figure 3-3: SCS Utilities Screen

Language

The SCS interface is programmed in limited languages. English is the default language setting.

By setting this configuration option, you can work on the SCS in the language of your choice.

Setting SCS Language

1) Press **F4** to access the Configuration screen.

2) Press the **Down Arrow** key to move the cursor to the **Language Choice** field.

3) In the **Language** field, press **Help** to display an option box with the available languages.

4) Press the **Up** or **Down Arrow** key to select a language, then press **Enter**.

5) Press **F2** to exit the SCS Configuration screen.

or

Press **Next** or **Previous Screen** to access other configuration screens.

Audible Feedback

The SCS custom keyboard does not have an audible click when you press a key. This option enables an audible click from the instrument every time you press a key on the SCS keyboard.

Setting Audible Feedback

1) Press **F4** to access the Configuration screen.
2) Press the **Down Arrow** key to move the cursor to the **Enable Audible Feedback** field.
3) In the **Audible Feedback** field, press **0** to turn the Audible Feedback off.

   or

   Press **1** to turn the Audible Feedback on (default).
4) Press **F2** to exit the SCS Configuration screen.

   or

   Press **Next** or **Previous Screen** to access other configuration screens.

Host Type

This field allows you to configure the instrument to communicate with either a PC workstation or an AIX workstation.

Changing Host Type

1) Press **F4** to access the Configuration screen.
2) Press the **Down Arrow** key to move the cursor to the **Host Type** field.
3) In the **Host Type** field, press **1** to select the PC workstation option (default).

   or

   Press **2** to select the AIX workstation option.
4) Press **F2** to exit the SCS Configuration screen.

   or

   Press **Next** or **Previous Screen** to access other configuration screens.

Time and Date

The SCS tracks the time of day and the calendar date.

Setting SCS Time and Date

1) Press **F4** to access the Configuration screen.

2) Press the **Down Arrow** key to move the cursor to the **Time** field.

3) In the **Hour** field, enter the *current hour*, using a 24-hour format (for example, 9 PM = 2100). Press **Enter** to accept the new value.

4) Enter the *current minutes*. Press **Enter** to accept the new value.

5) Enter the *current day*. Press **Enter** to accept the new value.

6) Enter the *current month*. Press **Enter** to accept the new value.

7) Enter the *current, four-digit year*. Press **Enter** to accept the new value.

8) Press **F2** to exit the SCS Configuration screen.

   or

   Press **Next** or **Previous Screen** to access other configuration screens.

SCS Firmware Update

You receive periodic program updates, or update media, along with installation instructions for these updates, from bioMérieux. When you perform an update, all the necessary SCS files are included in the product release.

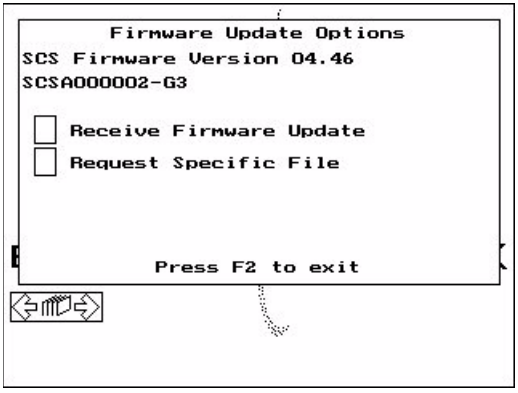


Figure 3-4: SCS Firmware Update Screen

The SCS firmware can be updated to enhance its functions. These updates are performed by connecting the SCS to the workstation using a cable.

There are two Firmware Update options:

Receive Firmware Update – This field allows you to request a complete firmware update from the workstation.

Request Specific File – This field allows you to request a specific file from the workstation. If the use of this field is neccessary, the appropriate procedure will be included in the instructions that were provided with the update media.

VITEK® 2 INSTRUMENT 4

Introduction

This chapter describes the hardware systems in the VITEK® 2 instrument. External Instrument Components on page 4-2 points out the controls and connections found on the instrument's exterior, and the doors by which you gain access to its interior. Instrument Hardware Components on page 4-5 describes the work stations and components in the instrument.

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External Instrument Components • 4-2

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Connections • 4-4

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User Interface System • 4-18

Keypad and Screen • 4-18

External Instrument Components

The following images contain a front and a left side view of the VITEK® 2 and VITEK® 2 XL instrument. Use the diagram to locate and familiarize yourself with the external controls and the access doors to the interior of the instrument.

Figure 4-1: The VITEK® 2 60 Instrument

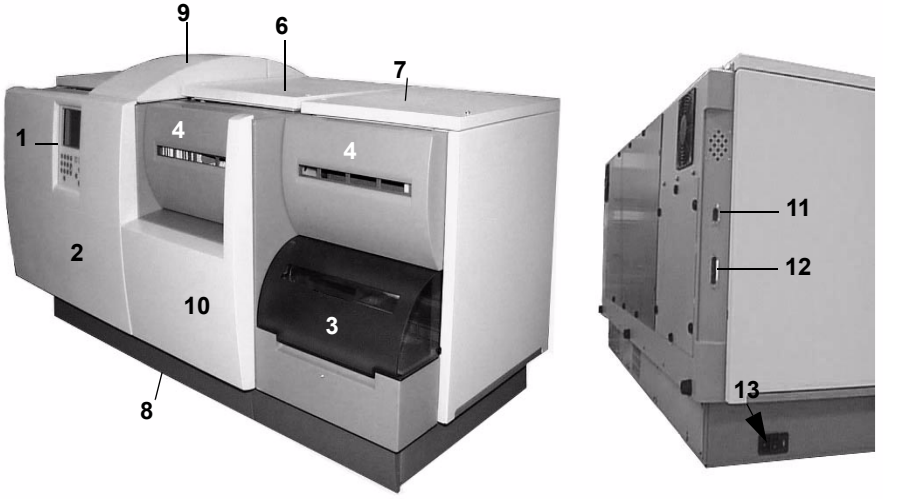

Figure 4-2: VITEK® 2 XL Instrument

Controls, Access Doors and Connections

CAUTION: All access doors should remain closed when processing cards.

LASER WARNING

All access doors and covers must remain closed when processing cards to avoid exposure to laser light.

1 — User Interface Screen and Keypad. This screen and keypad comprise the User Interface system. See page 4-18 for detailed information.

2 — Front Access Door. Provides access to the diluter, pipette tip container, and a portion of the test card transport system. The door opens from the right side.

3 — Cassette Load/Unload Door. Provides access to the Cassette Load/Unload station. The door slides up to open. A locking mechanism prevents opening of this door at inappropriate times.

4 — Waste Collection Door. Provides access to the Waste Collection Station where ejected test cards are removed from the instrument. The door is held in place magnetically and lowers from the top.

5 — Top-Right Access Door. Provides access to the optics and the carousel. The door lifts from the front and stays in the open position.

Note: *The top-right access door cannot be opened unless the Waste Collection door (**4,** Figure 4-1 and Figure 4-2) is opened first.*

Note: *This door is secured by two screws, and requires a flathead screwdriver to open.*

6 — Top Access Door Section A. VITEK® 2 XL only. Provides access to the optics and carousel for Section A.

7 — Top Access Door Section B. VITEK® 2 XL only. Provides access to the optics and carousel for Section B.

8 — Bottom Access Door. Provides access to the drip pan. The door is held in place magnetically and must be pulled down to open.

9 — Saline Access Door. Provides access to the sterile saline bag. The door lifts from the front and stays in the open position.

10 — Center Front Sliding Door. VITEK® 2 XL only. The Cassette load/unload door (**3**) must be opened before this door can be opened.

Connections

11 — UPS Connection. This cable connector port connects VITEK® 2 to an uninterruptable power supply (UPS). The connection allows the UPS to notify the VITEK® 2 instrument of a power loss so the VITEK® 2 can start appropriate procedures.

12 — Workstation Connection. This connector port accepts the cable that connects the VITEK® 2 instrument to the workstation computer.

13 — AC Power Switch and Cord Receptacle. This switch supplies power to the VITEK® 2 instrument. The cord receptacle accepts the power cord that is connected to the electricity source.

Turning on the VITEK® 2 Instrument

Note: *Refer to the environmental and electrical specifications for the VITEK® 2 instrument in Appendix A before starting the instrument.*

Startup Procedure

1) Make sure the VITEK® 2 instrument has been connected to an appropriate power supply using the power cord supplied with the instrument.

2) Press the AC power switch to the ON position (**13**, Figure 4-2).

The instrument goes through an initialization sequence that includes several self tests. During this time, VITEK® 2 is also bringing the carousel area up to its specified temperature for test card incubation.

After a few minutes, the VITEK® 2 Status screen appears. The **Status** field at the top of the screen should show a status of **Warming** or **OK.** The **Warming** status means that the carousel temperature is not yet within its specified range. This can take several minutes.

VITEK® 2 is ready to begin processing cards when the Status field shows **OK.** (For more information about the Status field, see the topic Instrument Status Field in Chapter 6).

Instrument Hardware Components

The VITEK® 2 instrument is an integrated system, combining the tasks of sample preparation, test card inoculation, and test card incubation and reading.

The parts and functions of the VITEK® 2 instrument can best be described by following a test card through the phases of a typical processing cycle. Table 4-1 summarizes this cycle, and shows you where you can find more details about a particular component of the VITEK® 2 instrument.

Table 4-1: Components Involved in the Test Card Processing Cycle

Component	Processing Phase	Information
Cassettes	Test card transport	page 4-6
Cassette Load and Unload Station	Test card transport	page 4-7
Boats	Test card transport	page 4-8
Bar Code Reader	Sample preparation	page 4-9
Button Memory Reader	Sample preparation	page 4-10
Dispenser/Pipettor Station	Sample preparation	page 4-11
Filler Station	Sample preparation	page 4-13
Sealer Station	Sample preparation	page 4-14
Test Card Incubation and Reading	Test card analysis	page 4-14
Carousel	Test card analysis	page 4-15
Optics	Test car analysis	page 4-16
Card Ejection	Test card transport	page 4-16
Waste Collection Station	Test card transport	page 4-17
User Interface System	All process phases	page 4-18

Smart Carrier Station (SCS)

The SCS is not a part of the VITEK® 2 instrument, but it is the station where the entire process begins. For complete details on the SCS, see Chapter 2.

Cassettes

BIOHAZARD WARNING

The boat should be considered as potentially contaminated and should be handled appropriately. Qualified laboratory personnel should take the usual precautions necessary for infectious agents.

The cassette is the main component of the test card transport system. It can hold up to 15 test cards with their inoculum test tubes. In systems using the Smart Carrier Station, the button memory chip on the cassette is used to store and transport data from the Smart Carrier Station to VITEK® 2.

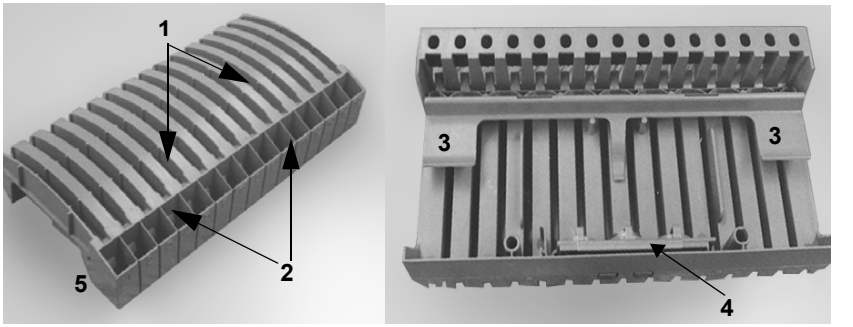

Figure 4-3: Cassette Components

1 — Test Card Slots. The top portion of a cassette is divided into 15 test card slots that can hold various combinations of VITEK® 2 test cards.

2 — Test Tube Holders. The front portion of a cassette has 15 wells that hold test tubes for inoculum.

3 — Test Tube Release. Test tubes are held securely in the cassette by a retaining bar. A release lever is provided for easy disposal of used test tubes.

4 — Button Memory. For systems using a Smart Carrier Station, each cassette is fitted with a special memory chip, called the button memory. When a cassette is on a Smart Carrier Station, the button memory stores the information that you enter for each test card. This information is read by a station in VITEK® 2, which marks the memory chip as being read, allowing the cassette to be reused.

5 — Cassette Base. The base of a cassette is specially shaped to:

- Fit snugly onto the base unit of the Smart Carrier Station. When properly fitted on the base unit, the contacts for the button memory are touching the contacts that protrude from the base unit.
- Fit into a boat. The shape of the cassette base matches the well on the top of a boat. This ensures that the two units move as one through VITEK® 2. The shape also ensures that the cassette can only be put into a boat in the proper orientation

Cassette Load and Unload Station

Load and unload cassettes from VITEK® 2 using this station. The station consists of the cassette load door (**1,** Figure 4-4) and a green indicator light (**2**). The door has a locking mechanism.

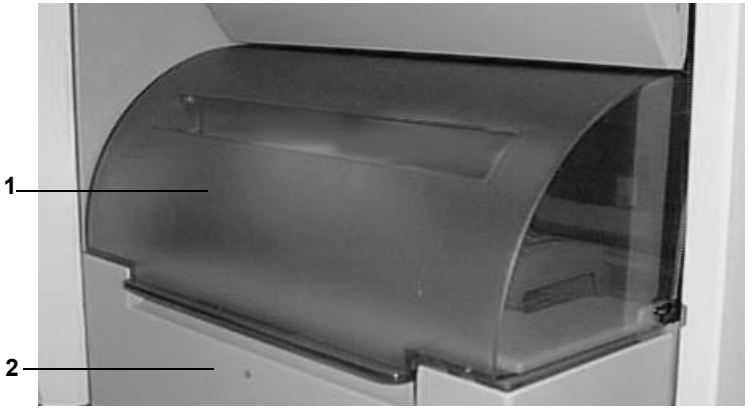

Figure 4-4: The Cassette Load/Unload Station

Table 4-2: Indicator Light States

Light Status	Error Condition and Resolution
On	The cassette load door is unlocked. You may open the door to load cassettes.

Table 4-2: Indicator Light States (Continued)

Light Status	Error Condition and Resolution
Off	The cassette load door is locked and cannot be opened.
Blinking	A boat with an empty cassette has arrived at the station. The cassette load door is unlocked. Open the door and remove the cassette. When you close the door, the blinking stops.

CAUTION: The VITEK® 2 test card transport system stops while the cassette load door is open. Be sure to close the door after loading or unloading a cassette.

BIOHAZARD WARNING

The boat should be considered as potentially contaminated and should be handled appropriately. Qualified laboratory personnel should take the usual precautions necessary for infectious agents.

CAUTION: Do not move or remove a boat from the instrument unless you are using the programmed function for this purpose. Doing so can cause an instrument jam.

Boats

The VITEK® 2 instrument contains four plastic trays called boats. These boats carry cassettes through the processing stations inside the VITEK® 2 instrument.

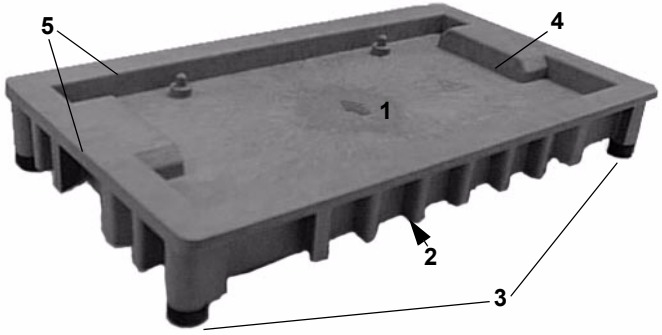

Figure 4-5: Boat Components

A boat, shown in Figure 4-5, has particular features that support its three major functions:

1— Test Card Transport. The top surface of a boat forms a specially shaped well into which a cassette is placed. The shape of the well conforms to the base of a cassette, providing it with a secure platform on which to ride. The two pins in the well ensure that the cassette is placed into the boat only in the proper orientation. An arrow is molded into the surface of the well to show the proper orientation of the boat when placed in the instrument.

2 — Notched Base. The base of each boat is notched in several places. These notches are used by the VITEK® 2 test card transport mechanisms that move the boats through the module.

3 — Base Supports. Each boat stands on four low-friction feet, providing a surface on which the boat can easily move.

4 — Spill Prevention. The well in the top of the boat catches any spills from the cassette.

5 — Test Card Filling. Above the cassette well, there is a flat surface that extends around the perimeter of the boat. This surface becomes the base of the vacuum chamber when the boat reaches the Filler station.

Bar Code Reader

After a cassette is loaded onto a boat, the test card transport system moves the boat past the bar code reader station. This station reads the information encoded on the bar code label found on each VITEK® 2 test card. The following information is included in the bar code:

Test Card Type — For example, a Gram Negative Susceptibility test card.

Investigational Use Only (IUO) flag — This tells VITEK® 2 if an experimental test card is being processed.

Test Card Expiration Date — This date is transferred to the workstation, which prints it on the laboratory report.

Test Card Lot Information and Sequence Number — This includes the test card's lot number to provide manufacturing traceability. The sequence number uniquely identifies a test card.

CAUTION: When handling VITEK® 2 test cards, make sure you do not deface the bar code in any way.

LASER WARNING

All access doors and covers must remain closed when processing cards to avoid exposure to laser light.

Button Memory Reader

The Button Memory Reader is a device that the VITEK® 2 instrument uses to read the test card information stored by the Smart Carrier Station in the memory chip on a cassette. VITEK® 2 uses this test card information in two ways:

- The test card type entered at the SCS is compared to the test card type that VITEK® 2 reads with its own bar code reader. This ensures that no changes were made in the position of any test card in the cassette.
- The accession ID, test card type, and the other fields entered at the SCS are sent to the computer. This information allows the software to link the test card results from VITEK® 2 to patient demographic data and any previous test results.

After the information is extracted from the button memory, VITEK® 2 marks its contents as **Read**. When the cassette is put on the SCS again, a button memory marked as **Read** is erased so the cassette can be used again.

CAUTION: The memory chip must be removed from the cassette before cleaning the cassette.

Dispenser/Pipettor Station

This station automatically prepares the organism dilution used for AST (Antimicrobial Susceptibility Test) cards. VITEK® 2 provides a significant time savings by ensuring that mated ID and AST cards are processed from the same sample.

Dispenser

The dispenser system, shown in Figure 4-6, delivers 2.5 mL of sterile saline into the test tube of each AST card in a cassette.

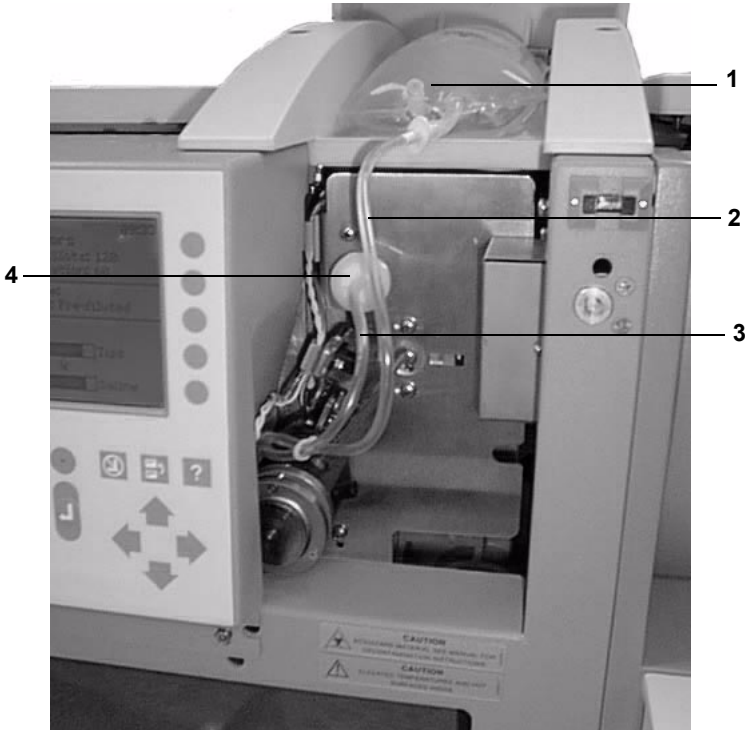

Figure 4-6: Dispenser System

Sterile Saline. The top of the VITEK® 2 instrument has a compartment designed to hold a one-liter bag of sterile saline (**1,** Figure 4-6). This is enough saline to process about 330 AST cards.

Dispenser Assembly. The dispenser assembly consists of a plastic dispensing chamber and two sections of plastic tubing. One section of tubing (**2**) leads from the dispensing chamber and is attached to the sterile saline bag. The other section of tubing (**3**) also leads from the dispensing

chamber but is attached to an air pump. It is fitted with a filter (**4**) to prevent particulate contamination.

Electromechanical Components (not shown). The electromechanical components control how the system works.

1) When an AST card is detected, a valve opens to allow saline to travel from its bag to the dispensing chamber.

2) An optical sensor detects when the chamber is full (2.5 mL) and closes the valve.

3) The dispensing chamber rotates into position over the AST card's test tube.

4) The air pump is activated, forcing the saline into the tube at a controlled rate that minimizes splashing.

Pipettor

The pipettor station transfers a preset volume of an organism suspension from its test tube into the test tube of its mated AST card.

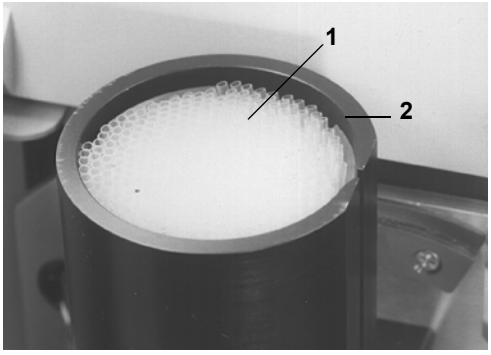

Figure 4-7: Disposable Pipettes

1 — Disposable Pipette Tips. To prevent contamination, VITEK® 2 uses single-use, disposable pipette tips.

2 — Container. The container holds up to 350 pipette tips. It has an internal mechanism that ensures proper delivery of each pipette tip to the displacement pump.

3 — Displacement Pump (not shown). The displacement pump withdraws a specified volume of inoculum for dilution in the inoculum tube of an AST card.

Note: *The displacement pump is not normally visible as it is located directly behind the interface screen and keypad.*

Displacement Pump Operation

The displacement pump is part of a larger assembly that performs the pipetting and transfer of the suspension when VITEK® 2 is in the Automatic dilution mode. Here is how it works:

1) The container drops a pipette tip into position.

2) The displacement pump assembly extends a hollow metal tube into the container, attaches a pipette tip to the tube, and withdraws the pipette tip from the container. The instrument checks to ensure that a pipette tip is attached.

3) The pump assembly rotates so the pipette tip is over the ID suspension test tube. The pipette tip is then lowered into the suspension. The instrument checks to make sure there is fluid in the ID test tube.

4) The pump draws the preprogrammed amount of suspension and withdraws the pipette tip from the test tube.

5) The cassette moves so that the susceptibility test tube is now under the pipette tip.

6) The pipette tip is lowered into the test tube and the pump dispenses the suspension into the tube where it mixes with the saline from the Dispenser.

7) The pipette tip is removed from its attachment and left in the sample tube for disposal.

Filler Station

At the Filler Station, all of the test cards in a cassette are inoculated with the suspension contained in their corresponding test tubes.

The Filler Station uses a vacuum chamber and pump. When the boat carrying a cassette reaches this station, the top of the vacuum chamber lowers onto the boat, so the boat serves as the base of the vacuum chamber.

1) The pump evacuates the air from the chamber. This forces the air inside each test card to escape via the transfer tube and bubble up through the suspension. The channels and wells inside of each test card are now at a vacuum.

2) After a short period, the vacuum is slowly released. The increasing air pressure inside the chamber forces the suspension in each test tube through the transfer tube and into the channels and wells of the test card.

Various temperature and air pressure sensors in the system monitor the inside of the vacuum chamber. VITEK® 2 ensures proper test card fills by monitoring these parameters throughout the entire cycle and controlling the rate at which the vacuum is drawn and released.

Note: *The seal on the vacuum chamber should be cleaned periodically. See the maintenance schedules and procedures in Chapter 7 of this manual.*

Sealer Station

CAUTION: The sealer station contains a wire that is heated during the sealing operation. Do not reach into the instrument during the sealing operation.

The Sealer station completes the functions inside VITEK® 2 that prepare the test cards for incubation and reading. This is accomplished by heat-sealing the transfer tube that delivered inoculum to the test card from its test tube. This seals off the contents of the test card.

As the boat and cassette move through this station, a heated wire comes in contact with each transfer tube. The plastic tube melts, causing most of it to separate from the test card and drop into the test tube. The portion that remains in the test card is sealed by the melting plastic.

Note: *The stub left from the transfer tube may be up to 0.1 inch (0.25 cm) long.*

Test Card Incubation and Reading

Once test cards are sealed, they are ready to be incubated and read. The test card transport system moves the boat and cassette into position for a mechanism, called the Card Loader, to place each test card into a slot on a carousel, where it remains throughout the reading cycle.

Carousel

The Carousel, shown in Figure 4-8, has a capacity of 60 test cards. During their time in the carousel, the test cards are incubated at an average temperature of 35.5 °C.

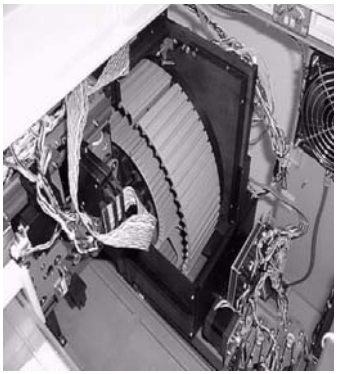

Figure 4-8: Carousel Placement

As the carousel rotates, each test card moves into the reading position every 15 minutes. A mechanical device called the Reader Head, shown in Figure 4-9, conveys the test card through the optics stations.

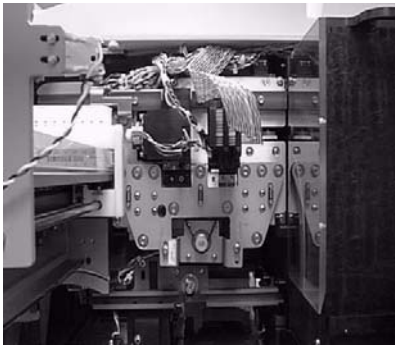

Figure 4-9: Carousel Reader Head

After the reading cycle, the test card returns to its slot in the carousel, where it continues to incubate until its next read cycle.

Note: *The carousel is divided into four sections so it can be easily removed for periodic cleaning.* *See Cleaning the Carousel on page 7-10.*

Optics

The VITEK® 2 instrument performs its identification and susceptibility analyses by continually monitoring the growth and activity of organisms inside the wells of the test cards. The optics system performs this function.

Transmittance Optics

The transmittance optics (**1**, Figure 4-10) use visible light to directly measure organism growth. These optics are based on an initial light reading of a well before significant growth has begun. Light transmittance samplings of the same well every 15 minutes measure organism growth by how much light is prevented from going through the well.

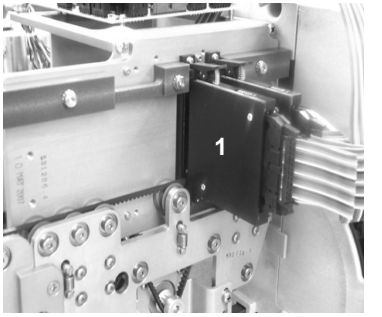

Figure 4-10: Optics

The optics use light emitting diodes (LEDs) that produce light at the appropriate wavelengths, and silicon photodetectors to capture the transmitted light. The system is self-calibrating.

Note: *The optics should be cleaned periodically.* *See Cleaning Optics (Normal Maintenance) on page 7-26.*

Card Ejection

The card ejection function permanently removes test cards from the carousel after their testing is completed. The mechanism that performs this function is the same drive belt system that moves the test cards through the reader. Instead of returning to the carousel, an ejected test card continues on to the Waste Collection Station.

The amount of time that cards are held before being ejected automatically from the carousel is set by an option in the System Configuration screen at the workstation computer. Cards can also be ejected at any time using a manual ejection function.

CAUTION: Do NOT re-insert ejected test cards into the VITEK® 2 instrument.

WARNING

Make sure that all test card processing has been completed before ejecting a test card.

Waste Collection Station

The card ejector removes test cards that have completed testing from the reader. These test cards are collected in a tray at the Waste Collection Station for removal from the VITEK® 2 instrument and disposal. The station, shown in Figure 4-11, holds up to 60 test cards. The instrument counts test cards as they fill the tray, and sends a message to the VITEK® 2 interface screen when the station is full. A sensor in the station detects when the tray has been emptied or if the tray is missing.

Figure 4-11: Waste Collection Station

Access the Waste Collection Station by opening the waste collection door on the front of the VITEK® 2 instrument.

Note: *Keep the Waste Collection Station door closed except when test cards are being removed from the station.*

Note: *Empty the waste collection tray after loading a new cassette into the instrument.*

Note: *Periodically remove the waste collection tray for cleaning.* *See Cleaning the Test Card Collection Tray on page 7-25.*

User Interface System

Throughout the entire processing cycle for test cards, communication between the user and the VITEK® 2 instrument is essential. The VITEK® 2 User Interface System provides the means of that communication.

Keypad and Screen

A keypad and screen are located on the front of the instrument. VITEK® 2 uses the screen to send messages about its operation, on-board disposables, and possible problems. Use the keypad to respond to the instrument instructions, to send commands to VITEK® 2, and to perform other functions. Figure 4-12 identifies the components of the keypad and screen.

Figure 4-12: The VITEK® 2 Keypad and Screen

1 — Option Buttons. Use these buttons to select menu options or other specified functions.

2 — Help (?) Key. Press this key at any time to access the error/message queue.

3 — Previous Screen Key. Use this key to:

- Exit from a screen or function to its menu.
- Return to a previous screen in a function.
- Go from a sub-menu to its previous menu.
- Go from the Main Menu to the Status screen.

4 — Undo Key. Use it to cancel the last action performed.

5 — Arrow Keys. Use these keys to:

- Scroll a screen or menu.
- Move the cursor on screen.

Note: *When **Arrow** keys are active, their icons appear on the display.*

6 — Enter Key. Use this key to complete data entries, or when instructed to do so on a screen.

7 — Numeric Keys. Use these keys to enter a number onto a screen.

CONFIGURING THE VITEK® 2 INSTRUMENT 5

Introduction

Configuration options allow you to operate the VITEK® 2 instrument in a number of different ways. This chapter explains not only how to set these options, but how each option affects the operation of the instrument, and therefore your laboratory workflow.

Certain configuration options affect only the physical interface and can be changed to suit your preferences. For example, you can adjust the contrast on the interface screen.

Other options affect how VITEK® 2 processes test cards, and therefore should be carefully considered before setting or changing them.

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- *Setting Configuration Options • 5-2*
- *Cassette Names • 5-3*
- *Instrument Name • 5-3*
- *Schedule Instrument QC Status • 5-4*
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Configuration Options

Configuration Overview

There are 12 configuration options in the VITEK® 2 user interface. They can be divided into two groups, depending on whether or not the option affects how the instrument operates. The group that affects instrument operation is composed of the following options:

Table 5-1: Configuration Options that Affect Instrument Operation

Option	Reference
Cassette Names	page 5-3
Instrument Name	page 5-3
Schedule Instrument QC Status	page 5-4
Cassette Mode	page 5-5
Dilution Mode	page 5-5
Bar Code Reader	page 5-6

The group of options that affect only the physical parameters of the user interface is composed of the following options:

Table 5-2: Configuration Options that Affect Only Physical Parameters

Option	Reference
Audible Alarm Enable	page 5-6
Audible Alarm Volume	page 5-6
Visual Alarm Enable	page 5-7
Audible Feedback Volume	page 5-7
Screen Contrast	page 5-7
Waste Tray Warning Level	page 5-8

Setting Configuration Options

Configuration options can be set or changed at almost any time. However, you should follow this simple workflow to ensure that you set your options correctly.

1) Read the descriptions contained in this chapter for each option.

2) Evaluate the effect that an option has on your workflow and decide how to set the option. This is especially important for the options in Table 5-1.

3) Set the options according to the choices made in Step 2, by following the procedures in this chapter.

4) Operate the system to validate the settings and evaluate the physical parameter settings for the options in Table 5-2.

5) Change any option as required.

Cassette Names

The **Cassette Name** option allows you to define up to 10 three-character VITEK® 2 "users", which can represent the technologists who process test cards, sections of the laboratory from which test cards originate, or any identification scheme you choose. On the VITEK® 2 workstation, you can then filter the test card directory view by **Cassette Name**, in order to view only the cards processed by a particular user.

The **Cassette Name** option is designed for workflows without a Smart Carrier Station (SCS). The **Cassette Name** that you define replaces the *cassette name* that would be read from the cassette's button memory. You should use this option if you do not have an SCS, or if you have a workflow that does not require the use of an SCS.

Note: *If the VITEK® 2 instrument is in Smart Carrier mode, the **Cassette Name** option cannot be accessed. If you attempt to use the option, the screen displays the message:*

```
This option is used with Cassette Only mode
```

For information on setting this option, see the procedure Using Option Boxes on page 5-11.

Instrument Name

The **Instrument Name** option allows you to name a VITEK® 2 instrument module. The name can contain up to 20 printable characters, including spaces. The **Instrument Name** can be helpful in those laboratories with more than one VITEK® 2 instrument to segregate, for example, specimen types or technologists. The **Instrument Name** also displays on the Directory window at the VITEK® 2 workstation.

The VITEK® 2 instrument names default to Instrument 1, Instrument 2, and so on. You should use this option if you have more than one instrument module. By assigning each instrument module a different name, you can view test card directories by the instrument in which they are being processed.

For information on setting this option, see the procedure Defining Character Sets on page 5-9.

Schedule Instrument QC Status

The QC Status is a report of the current incubator temperature and the status of the optics systems. The report is sent to the VITEK® 2 workstation where it is recorded with the date and time the report was taken.

The configuration option allows you to schedule up to three times of day when a QC report is taken and recorded at the workstation.

The Instrument Quality Control Status includes two parameters:

- Carousel Incubator Temperature
- Optics Systems

The instrument continuously monitors these parameters so their status can be determined at any time. The user interface provides a function, called **Display Instrument QC Status**, to access this information.

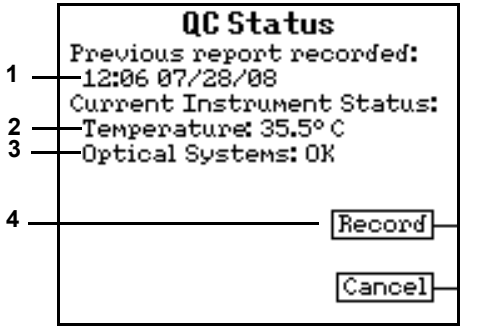

Figure 5-1: The Instrument QC Status Screen

1 — This field displays the time and date that the previous QC status was recorded. The field is blank if this function has never been used before.

2 — Temperature. For VITEK® 2, this field displays the current carousel temperature in degrees Celsius. For the VITEK® 2 XL, the temperatures for carousel A and B are displayed.

3 — Optical Systems. This field displays the status of the transmittance optical system.

4 — Record. Press this button to transmit the QC status information to the workstation. During the transfer the screen displays the message:

```
Recording QC Report
```

The instrument user interface contains a function with which you can manually record a QC Status. You can set this option if you want the report recorded automatically. For example, you can have the report recorded at the same time every day.

For information on setting this option, see the procedure Setting Time for QC Status on page 5-10.

Cassette Mode

The **Cassette Mode** tells the VITEK® 2 instrument whether or not you use a Smart Carrier Station, and is critical to instrument operation. The option enables or disables the instrument's Button Memory Reader, a device that reads information stored in the button memory.

The **Cassette Mode** option defaults to Smart Carrier, meaning that an SCS is being used. Use this option to change the mode to Cassette Only if your laboratory does not have an SCS.

For information on setting this option, see the procedure Using Option Boxes on page 5-11.

Dilution Mode

The **Dilution Mode** option can be set to either Automatic or Pre-diluted. In the Automatic mode, the Dispenser/Pipettor station in the VITEK® 2 instrument automatically prepares the inoculum for AST cards that have matching ID cards. In the Pre-diluted mode, the Dispenser/Pipettor station is disabled.

If you use an SCS, the operation of the Dispenser/Pipettor station is determined by the information in the cassette's button memory.

Note: *If the VITEK® 2 instrument is in Smart Carrier mode, the Dilution Mode option cannot be accessed. If you attempt to use the option, the screen displays the message:*

```
This option is used with Cassette Only mode
```

However, if you are not using an SCS, this option must be set as follows:

- To Automatic if you want VITEK® 2 to prepare your AST card inocula.
- To Pre-diluted if you prepare AST card inocula manually.

Note: *If the instrument is in Cassette Only mode, you can use the* ***Cassette Setup*** *function (Main Menu) to process individual cassettes in the dilution mode opposite to the configuration setting.*

BIOHAZARD WARNING

Biohazardous spills can occur inside the VITEK® 2 instrument if the Dilution Mode option is not properly set. This is especially true if pre-diluted samples are used with the mode set to Automatic.

For information on setting this option, see the procedure Using Option Boxes on page 5-11.

Bar Code Reader

The VITEK® 2 instrument has a bar code station that reads the bar code labels on the test cards. If the reader becomes misaligned, or if some other error occurs in the station, you may get repeated error messages about bad bar codes.

Use this option to disable the bar code reader if there is a problem with the station. Do NOT use this option unless you think there is a problem in the bar code reader station.

For information on setting this option, see the procedure Using Option Boxes on page 5-11.

Audible Alarm Enable

The instrument sounds an audible alarm to alert you to an error condition. The alarm stops temporarily when you press any key on the instrument keypad, sounding again if you do not access the message queue.

The **Audible Alarm Enable** option defaults to Enabled. The option to disable the alarm is provided for cases where the instrument is located very near the workstation. Since the workstation also sounds an alarm, disabling the instrument's alarm eliminates this redundancy.

For information on setting this option, see the procedure Using Option Boxes on page 5-11.

Audible Alarm Volume

The volume of the audible alarm can be adjusted higher or lower to account for laboratory conditions.

The default setting for the alarm volume is at the midpoint of its range. Use this option to make the appropriate adjustments as required. The option includes a test function so that you can hear the alarm while changing it.

For information on setting this option, see the procedure Setting a Range Value on page 5-12.

Visual Alarm Enable

The instrument causes the interface screen display to blink to alert you to an error condition. The blinking terminates when you press any key on the instrument keypad.

Since the VITEK® 2 instrument and workstation each have an audible alarm, the visible alarm may be unnecessary. If so, use this option to disable the alarm.

CAUTION: Do not disable both the audible and visual alarms on the instrument unless it is located very near the workstation. Doing so makes it more difficult to know that an error condition exists.

For information on setting this option, see the procedure Using Option Boxes on page 5-11.

Audible Feedback Volume

The VITEK® 2 instrument interface uses a touch pad type of keypad. It sounds an audible click when you press each key. The volume of the click can be adjusted to account for laboratory conditions.

The default setting for the Audible Feedback volume is at the midpoint of its range. Use this option to make the appropriate adjustments.

For information on setting this option, see the procedure Setting a Range Value on page 5-12.

Screen Contrast

The VITEK® 2 user interface screen uses an LCD display. This option controls the amount of background contrast on the display.

Viewing of a LCD screen can be enhanced by changing the contrast under certain lighting conditions. Use this option to change the screen if conditions require it.

For information on setting this option, see the procedure Setting a Range Value on page 5-12.

Waste Tray Warning Level

The VITEK® 2 instrument displays a warning message when the Waste Collection Tray reaches full capacity. Use this setting to adjust the amount of advance warning the instrument will provide.

When the Waste Tray Warning Level is set to zero, the VITEK® 2 instrument will issue the warning as soon as a card is loaded into the instrument that would overfill the Waste Collection Tray when it is completed. As the value of the Waste Tray Warning Level is increased, the instrument will allow that number of cards to be loaded into the VITEK® 2 instrument above the capacity of the waste tray before the warning is generated. If the Waste Tray Warning Level is set to 60, the instrument will not issue any warnings, it will only issue an Alarm when a card cannot be unloaded due to a full Waste Collection Tray.

For information on setting this option, see the procedure Setting a Range Value on page 5-12.

Using the Interface

There are 12 configuration options, but only four different procedures for setting them, depending on the interface used. The four interfaces used and the applicable configuration options are shown in Table 5-3.

Table 5-3: Types of Interfaces for Configuration Options

Type of Interface	Application Configuration Option	Reference
Character set	• Cassette Names • Instrument Name	page 5-9
Set time	Schedule QC Status	page 5-10
Option box	• Cassette Mode • Dilution Mode • Bar Code Reader • Audible Alarm • Visible Alarm	page 5-11
Set range value	• Audible Alarm Volume • Audible Feedback Volume • Screen Contrast • Waste Tray Warning Level	page 5-12

All of the configuration options for VITEK® 2 are on the **Configuration** menu. You access this menu using the path:

Main Menu > **Utilities** > **Configuration**

The VITEK® 2 Main Menu looks like this:

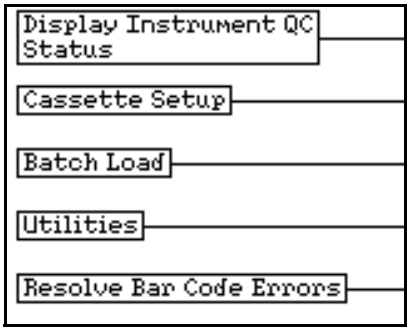

Figure 5-2: VITEK® 2 Main Menu

Defining Character Sets

Use this procedure for the Cassette Names and Instrument Name configuration options. Character sets can include any of the characters provided on the character selection, plus the 10 digits from the keypad.

1) Select the **Cassette Names** or **Instrument Name** configuration options using the path:

Main Menu > **Utilities** > **Configuration**

2) Choose **Cassette Name** or **Instrument Name**.

For the Cassette Names option, the following screen appears:

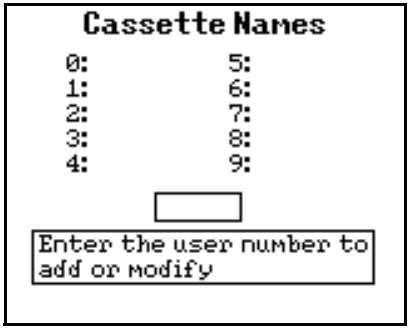

Figure 5-3: Cassette Names Configuration Screen

Note: *This screen does not appear for the* ***Instrument Name*** *option.*

3) Press a *number key* to select one of the ten cassette name positions, and then press **Enter**.

The Character Selection screen appears:

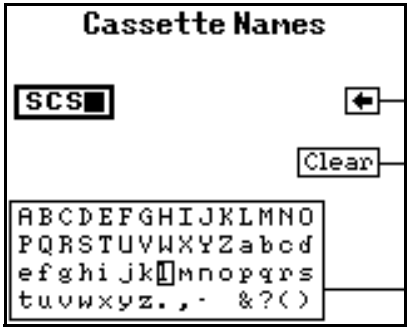

Figure 5-4: Character Selection Screen

Note: *This screen is similar for both the* ***Cassette Names*** *and* ***Instrument Name*** *options.*

4) Select a letter using the **Arrow** keys and then press the *option button* for the character box.

If you make a mistake, press **Backspace**.

Setting Time for QC Status

The function allows you to set up to three times during the day at which an instrument QC report is sent to the workstation.

Access this function using the path:

Main Menu > **Utilities** > **Configuration > Schedule QC Status**

The following screen appears:

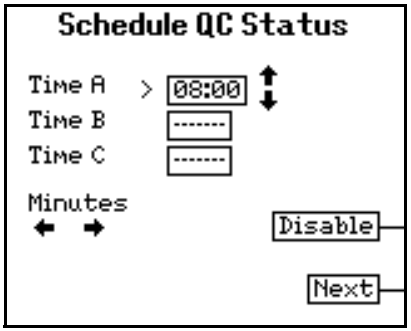

Figure 5-5: Schedule QC Status Screen

The time fields operate on a 24-hour clock. Times A, B, or C are disabled until you schedule the QC Status.

Note: *The **Left** or **Right Arrow** keys beneath Hours/Minutes allow you to toggle between **Hours** and **Minutes** when setting the time.*

To set the Hour for Time A:

1) Press the **Left Arrow** key until **Hours** displays.

2) Use the **Up** or **Down Arrow** keys to set the *hour*.

To set the Minutes for Time A:

1) Press the **Left Arrow** key until **Minutes** displays.

2) Use the **Up** or **Down Arrow** keys to set the *minutes*.

3) To schedule another QC Status report, select **Time B** by pressing the **Next** button.

4) To exit the function press **Enter**.

Using Option Boxes

This procedure applies to the following configuration options:

- Cassette Mode
- Dilution Mode
- Bar Code Reader
- Audible Alarm Enable
- Visual Alarm Enable

1) Access one of the above configuration options using the following path:

Main Menu > Utilities > Configuration

2) Press **Up** or **Down Arrow** to choose an option.

A screen similar to Figure 5-6 appears.

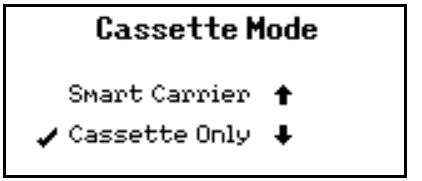

Figure 5-6: Option Box Screen

3) To change the current setting, press the **Up** or **Down Arrow** keys.

Setting a Range Value

This procedure applies to the following configuration options:

- Audible Alarm Volume
- Audible Feedback Volume
- Screen Contrast
- Waste Tray Warning Level

1) Access one of the above configuration options using the following path:

Main Menu > **Utilities** > **Configuration**

2) Press **Up** or **Down Arrow** to choose an option in the range (see Figure 5-7).

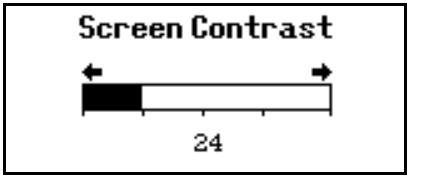

Figure 5-7: Range Value Screen

3) Change the range value by pressing the **Left** or **Right Arrow** keys.

The bar graph and the numeric value change, and the actual parameter changes in response to this action.

Note: *Do NOT set the screen contrast to either end of its available range. Doing so may make the screen unusable.*

Note: *For the Audible Alarm Volume parameter, a test button sounds the alarm.*

PROCESSING VITEK® 2 TEST CARDS 6

Introduction

This chapter contains the procedures you need to process VITEK® 2 test cards. The chapter begins with three introductory sections that provide reference information about the VITEK® 2 Status screen, the VITEK® 2 Menu system, and the Smart Carrier Station interface.

The next two sections contain suggested workflows and the procedures for working either with or without a Smart Carrier Station (SCS). The final section deals with unloading test cards from the instrument.

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Instrument Status Screen

You use the Status screen more often than any other screen in the VITEK® 2 user interface. Since it is so basic to the workflow, the Status screen is very easy to display and in many cases, the interface displays it automatically.

Displaying the Status Screen

There are three ways to display the Status screen:

- Automatically displays at the end of the instrument's power up initialization process.
- Automatically displays from the Main Menu whenever that menu is left unattended for more than one minute.
- Displays from the Main Menu by pressing the **Previous Screen** key.

Instrument Status Field

The **Status** field appears at the top of the VITEK® 2 Status screen.

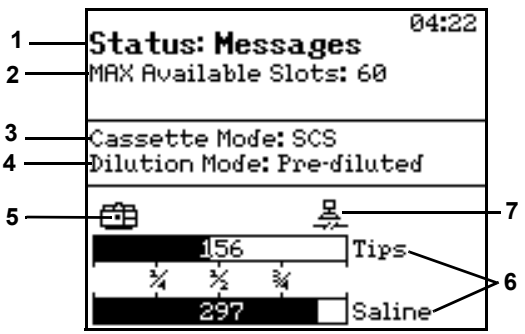


Figure 6-1: VITEK® 2 Status Screen in Cassette Only Mode

The **Status** field (**1**, Figure 6-1) displays one of the following:

- **OK.** This status means that all of the subsystems in the instrument are working normally, and that the instrument is ready to accept test cards for processing.
- **Warming.** This status is seen after the instrument is turned on. It means that the incubation temperature in the Reader Station has not reached its specified temperature. Test cards cannot be processed until this status changes to `OK`.

- **Messages.** This status indicates that there is an error message in the error/message queue that has not been viewed. Press the **Help (?)** key to view the error/message queue.
- **Errors.** This status appears after the error/message queue is accessed if the error condition has not been resolved. This status can be cleared only by resolving the condition that generated the original message.
- **Cleaning.** This status indicates that either all four boats, or at least one carousel section, have been removed for cleaning. Test card processing cannot resume unless all carousel sections, or at least one boat, are replaced.

Non Standard Card Reading Mode

A large X will be displayed over the Status screen when the instrument is configured in a Non Standard Card Reading mode. Non Standard Card Reading mode is for diagnostic troubleshooting by trained bioMeriéux Field Service Engineers only. If the instrument is configured in a Non Standard Card Reading Mode, do not process any cards and contact bioMeriéux immediately.

Figure 6-2: VITEK® 2 Status Screen in Non Standard Card Reading Mode

Card Capacity

The **MAX Available Slots** field (**2**, Figure 6-1) indicates the number of unoccupied slots in the instrument. You can load one or more cassettes containing up to that number of test cards. If you load more than that number, some of the test cards will not be processed unless additional slots become available by the time the test cards reach the carousel.

The number you see in the **MAX Available Slots** field depends on the VITEK® 2 instrument you have and the optical configuration of the instrument.

Table 6-1: Optical Configurations

Instrument/Max Available	Optical Configuration
VITEK® 2 MAX Available Slots: 60	• set of transmittance optics
VITEK® 2 XL MAX Available Slots: 120 Available ID Slots: 60	• ID transmittance optics (Section A) • AST transmittance optics (Sections A & B)

Cassette Name Field

When the instrument is in Cassette Only mode (**3**, Figure 6-1)**,** this field displays the name of the most recently used cassette. That cassette name is applied to all cassettes unless you elect to change it. When the instrument is in Smart Carrier mode, the field displays the name **SCS**.

Dilution Mode Indicator

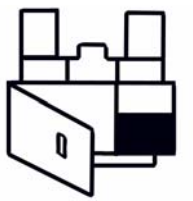
The Dilution Mode Indicator field (**4**, Figure 6-1) displays when the instrument is in Cassette Only mode. The field then tells you whether the instrument is set to the Automatic or Pre-Diluted dilution mode. This field should be checked before loading a cassette.

BIOHAZARD WARNING

Biohazardous spills can occur inside the VITEK® 2 instrument if pre-diluted samples are used with the mode set to Automatic. All organism suspensions should be considered as potentially infectious. Qualified laboratory personnel should use acceptable procedures for biohazardous material.

Status Screen Icons

The area on the Status screen just above the disposables graphs is reserved for the Status screen (**5**, **7**, Figure 6-1) icons.



•**VITEK® 2 Instrument Icon.** This icon represents the VITEK® 2 instrument. It shows when one of the access doors is open. These include the front access door on the front of the instrument, and the top access door.

•**VITEK® 2 XL Instrument Icon**. This icon represents the VITEK® 2 XL instrument. It shows when one of the access doors is open. These include the Section A top access door, Section B top access door, and the center front sliding door.

•**Cassette Icon.** An icon graphic of a cassette appears while a cassette is processing through the Bar Code Reader and Button Memory Reader stations. Its presence reminds you to stay near the instrument to ensure that the cassette does not experience any load errors.

•**Power Fail Icon.** This icon indicates that the instrument is being powered by the UPS battery only. While the instrument is in this condition, no new cassettes may be loaded. Cassette processing continues for 20 minutes, or until the UPS battery runs low, whichever comes first.

•**Low Battery Icon.** This icon indicates the UPS has low batteries. All processing is halted immediately.

•**Lost Communications Icon.** This icon indicates the instrument has lost communications with the host computer. The amount of time after host communications has been lost before an error is generated is 1 hour.

Monitoring Pipette Tips and Saline

The VITEK® 2 instrument uses pipette tips and saline (**6**, Figure 6-1) for automatic dilution of susceptibility inocula.

For each disposable, the Status screen displays a bar graph and number similar to the one shown in Figure 6-3:

Figure 6-3: Pipette Tips Status

As the disposables are used, the bar graphs begin to decrease. The graphs are marked to show levels of ¼, ½, and ¾ capacity. The number associated with the graph (156, in this example) decreases at the same time. When the number goes under 40, the value changes to **Low**.

Note: *For pipette tips, the number refers to the number of available tips. For saline, the number refers to the available number of aliquots.*

CAUTION: The disposable monitors should be used as an approximate indicator. Care should be used to prevent running out of either disposable during test card processing.

VITEK® 2 Menu System

All of the functions used on the VITEK® 2 instrument are available through the menu system. The system is composed of a Main Menu and a set of five submenus.

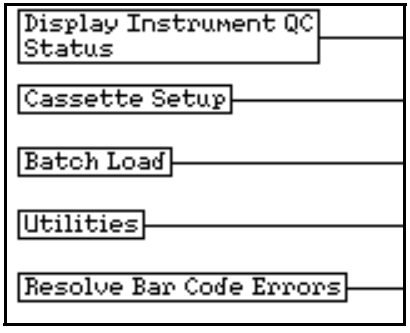


Figure 6-4: VITEK® 2 Main Menu

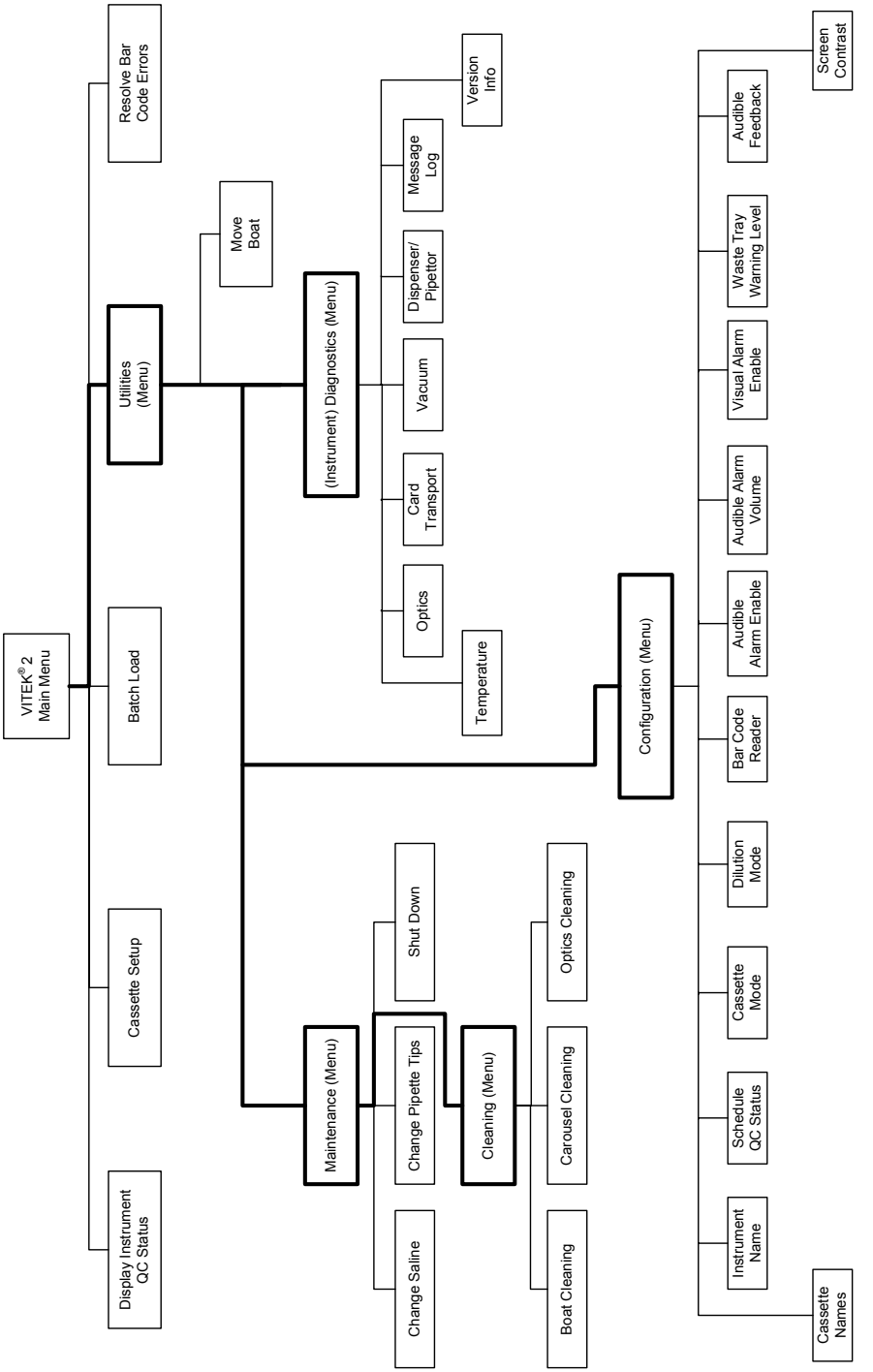


Figure 6-5: Detailed Structure of the VITEK® 2 Menu System

In Figure 6-5, the menu structure is shown with all of the function options added. Bold lines show the menus and pathways between them.

This manual describes the pathway to a specific function by naming each menu to access, with the menus separated by arrows. For example, the pathway to the **Change Saline** function on the Maintenance menu would be shown as follows:

Main Menu > **Utilities** > **Maintenance** > **Change Saline**

Frequently Used Keys

Option Buttons. There are five round buttons located along the right side of the user interface screen. When a menu or function option appears on the screen, you press the corresponding option button to access that menu or function.

Previous Screen Key. This key has three actions, depending on what displays on the screen.

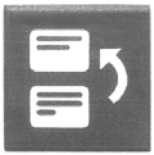


Figure 6-6: Previous Screen Key

- If a function displays on the screen, press **Previous Screen** to return the display to the menu from which the function was selected.
- If a menu displays on the screen, press **Previous Screen** to return the display to the previous menu.
- If the Main Menu displays on the screen, press **Previous Screen** to return the display to the Status screen.

About the Smart Carrier Station (SCS)

Advantages of Using SCS

The SCS is a labor-saving device that provides several advantages for your laboratory workflow.

Bar Code Scanner. The bar code scanner allows you to utilize the bar codes that are printed on the test cards and the SCS *Job Aid Card*. The **Test Card**

Type, **Organism**, **Offline Tests**, and **Modifier** fields can be entered without having to use the keyboard. If your laboratory uses bar codes for accession number of specimens, these can also be entered using the scanner.

Cassette. The cassette helps you organize your work. Each cassette has 15 slots for test cards and 15 corresponding wells for specimen test tubes. Information entry using the SCS bar code scanner or keyboard is organized by slot, which allows you to create a simple workflow. For example, using the bar code scanner, you could:

- Scan the accession ID, and place a specimen test tube in its well.
- Scan the test card, and place it in the corresponding slot.
- Scan the *Job Aid Card* for optional fields such as organism, offline tests, or modifiers.

Matching ID and AST Cards. When the SCS computer sees an AST card, it looks at the card in the previous slot. (For Gram negative AST cards, the previous *two* slots are included.) If an ID card with the same accession number is found, the cards are matched into a single group. Matched ID/AST card groups provide two advantages:

In Automatic Dilution mode, the inoculum for the AST card is created automatically in the VITEK® 2 instrument.

The organism identification called by the ID card is automatically applied to its matching AST card. (Two Gram negative AST cards can be matched to a Gram negative ID card; only one Gram positive AST card can be matched to a Gram positive ID card.)

SCS Cassette ID. In larger laboratories, using multiple Smart Carriers, the Cassette ID field provides an automatic trace between the test card and a specific SCS. Each SCS is given a three-character name (Cassette ID). That name is applied to every test card that is processed through the station. When you look up a test card on the VITEK® 2 directory, the source of any test card is instantly known. Smart Carriers can be named for the technologists using them, for a laboratory location, or for the types of specimens processed through them.

Safety. The cassette portion of the SCS provides a safe and convenient method of transporting multiple test cards from the workbench to VITEK® 2. Once a sample is placed in the cassette, the technologist never has to touch it again.

Security. The SCS provides an extra measure of security for your test card/specimen information. After a cassette is placed in VITEK® 2, a bar code reader in the instrument reads the bar code on the test card, and compares that information with the information it read from the cassette. Any

discrepancies in test card type or position in the cassette are reported to the user so that corrective action can be taken.

Cassette Edit Screen

The Cassette Edit screen provides an interface for entering test information. This screen is repeated for each cassette slot.

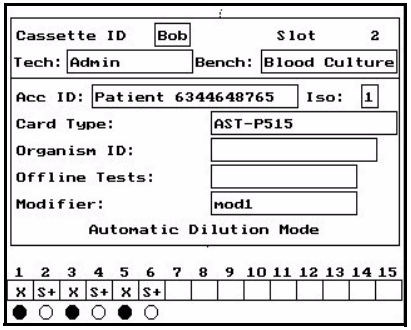

Cassette ID Bob Slot 2
Tech: Admin Bench: Blood Culture
Acc ID: Patient 6344648765 Iso: 1
Card Type: AST-P515
Organism ID:
Offline Tests:
Modifier: mod1
Automatic Dilution Mode
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
X S+ X S+ X S+

Figure 6-7: Fields of the Cassette Edit Screen

- **Cassette ID.** This field contains the cassettte identification string that will identify the cassette that is being edited. The Cassette ID allows test information to be searched on the workstation computer.
- **Bench.** (When Host Type is configured as PC). This field contains the bench name that will be applied to the cassette that is being edited.
- **Tech.** (When Host Type is configured as PC). This field contains the Setup Technologist ID that will be applied to the cassette that is being edited.
- **Acc ID.** This field allows the entry of an Accession ID to identify a specific specimen. You may enter up to 20 alphanumeric characters or spaces. Entry into this field is required before other test specific information can be entered. This information is also referred to as a Lab ID.
- **Isolate Number.** Field that defaults to a value of **1** and is normally skipped during data entry. To replace the default, move the cursor to this field using the **Up Arrow** key.
- **Test Card Type.** This field is used to identify the type of test card that is to be placed in the cassette slot.
- **Organism ID.** Field used for identifying an organism in an AST card.
- **Offline Tests.** Field that holds results of off-line tests performed for some test cards.

- **Modifier**. Field used for organism modifiers. Six generic entries, **mod1** to **mod6**, are preloaded. When this data reaches the workstation computer, the generic entry is converted to one of the first six corresponding entries in the Organism Modifier table of the bioLIAISON® database.
- **Dilution Mode.** The current dilution mode setting is displayed to allow quick verification. Refer to Figure 3-2 for instructions on how to change this setting.
- **Slot Indicator**. The slot indicator is the set of boxes at the bottom of the Cassette Edit screen (see Figure 6-7). The information in the slot indicator is read as follows:

  1) A number corresponding to the currently displayed slot appears over the appropriate box.

  2) The row of boxes is filled in as data is entered.

  3) These boxes are empty unless the user has entered data previously. A box in the row is filled automatically when the user enters data into the **Card Type** field. Indicators are:
  - I+ = Gram positive ID
  - I- = Gram negative ID
  - IA = ANC ID
  - IY = yeast ID
  - IB = bacillus ID
  - IH = haemophilus ID
  - S+ = Gram positive susceptibility
  - S- = Gram negative susceptibility
  - SY = yeast susceptibility
  - X = Indicates the position of the inoculum tube for a susceptibility test without a preceding mated ID when in Automatic Dilution mode. This slot must not contain a card.

Understanding the Slot Indicator

A shaded circle appears under a box when the SCS determines the test card in the slot requires an organism suspension. A completely open circle appears under a box when the test card in the slot requires an empty tube. Empty tubes are used for AST cards when the SCS is set to Automatic Dilution mode.

SCS Functions

Table 6-2 summarizes the functions that can be performed while entering data, and the use of the special function keys.

Table 6-2: Summary of SCS Functions

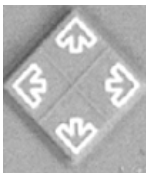
Key	Name	Function(s)	How To Use It
	Help (?)	Display context-sensitive help screens and data field option boxes.	Press **Help (?)**.
	**Up/Down** or **Left/ Right Arrow** key	Move between fields.	Press the **Up/Down** or **Left/Right Arrow** keys.
		Access the **Isolate Number** field.	Press the **Left** or **Up Arrow** keys to move to the **Isolate Number** field.
	Next or **Previous Slot**	Display an adjacent slot.	Press **Next** or **Previous Slot**.
	F1	Copy data from a previous slot to the current slot.	Press **F1** to copy the appropriate data from the previous slot.
	F2	Exit a screen.	Press **F2**.
	F3	Display the Summary screen.	1) Press **F3** to display the first summary screen. 2) Press **Next** or **Previous Slot** to display the second summary screen.
	F4	Display the Configuration screen.	Press **F4**.
	F6	Display the Flex Panel Entry screen.	Press **F6**.
	F8	Erase the data in the current field.	Press **F8**.

Table 6-2: Summary of SCS Functions (Continued)

Key	Name	Function(s)	How To Use It
	F9	Erase the data for a slot. ***Note:*** *This function also erases data in any successive linked slots.*	1) Press **F9**. A confirmation window appears. 2) Press **F1** to erase the data.
	F10	Erase all the data in the button memory chip.	1) Press **F10**. A confirmation window appears. 2) Press **F1** to erase the button memory chip.

Note: *The **F7** key is currently unassigned.*

Option Boxes

The **Organism ID**, **Offline Test**, and **Modifier** fields are restricted, that is, they accept only certain data. When entering data manually via the keyboard, option boxes provide access to the acceptable data entries.

Organism ID

This field has several option boxes, depending on the AST card type you enter in the **Card Type** field. For example:

Positive

Organism ID	
>	staaur
	staneg
	entspp
	strpre

Negative

Organism ID	
>	esccol
	promir
	provul
	pseaer

Figure 6-8: Organism ID Options

Gram Positive Susceptibility Card

Offline Test Result Screen

The contents of the option boxes for this field depend on the type of card you enter in the **Card Type** field. For example, the option box for a Gram positive susceptibility card would be similar to the following:

Offline Tests		
>	—	blac
	+	blac

Figure 6-9: Offline Tests Option Box

ANC Identification Card

Offline Test Result Screen

The Offline Test Result screen allows entry of values that are specific to Anaerobic and Corynebacteria (ANC) tests. Use the **Up** and **Down** keys to change fields.

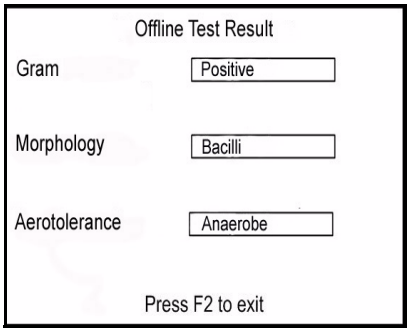


Figure 6-10: Offline Test Result Screen

Gram

The Gram field provides an option box that allows the entry of Gram stain information for the current test.

Allowed options are positive, negative, or variable.

Morphology

The Morphology field provides an option box that allows the entry of morphology values associated with the current test.

Allowed options are cocci, bacilli, or coccobacilli.

Aerotolerance

The Aerotolerance provides an option box that allows the entry of aerotolerance values associated with the current test. Allowed options are aerobe, anaerobe, or facultative.

Modifier

The option box for the **Modifier** field contains six default entries, **mod 1** to **mod 6**. When this data reaches the workstation computer, the entry is matched to one of the first six entries in the Organism Modifier table of the bioLIAISON® database.

Selecting an Entry Using an Option Box

1) Use the **Up** or **Down Arrow** key to move the cursor into the correct field.
2) Press the **Help (?)** key to access the option box for the field.
3) Use the **Up** or **Down Arrow** key to move the selection pointer (>) to the correct data entry.
4) Press **Enter** to return to the data screen.

Bar Code Scanner

The bar code scanner reduces the time required for data input. If your laboratory uses bar codes to identify patient specimens, these can be scanned to enter the accession ID.

The required bar codes for the **Organism**, **Offline Test**, and **Modifier** fields have been printed on the SCS *Job Aid Card*.

Bar code labels on every test card allow you to scan in the entry for the **Card Type** field. Additional information from this bar code is also stored in the cassette memory. This information helps VITEK® 2 properly identify and process each test.

Processing Test Cards Using the Smart Carrier Station

Note: *If your system does not have an SCS, refer to the section* *Processing Test Cards in Cassette Only Mode on page 6-21*.

Configuration Options for Smart Carrier Workflow

Before using the SCS, make sure that the following options are properly set:

- **On the Smart Carrier Station.** All of the configuration options on the SCS should be set. The most important of these is the Dilution Mode. Make sure that it corresponds to how susceptibility inocula are processed for this cassette. See AST Dilution Mode on page 3-5.

- **On the VITEK® 2 Instrument.** The most important configuration option for using the SCS is the **Cassette Mode**. This option must be set to **Smart Carrier**.

Smart Carrier Workflow

Table 6-3 provides a general workflow for using the SCS. This workflow assumes that you have:

- selected the VITEK® 2 test cards to process
- decided whether to prepare susceptibility suspensions manually or automatically using VITEK® 2

Note: *If you choose to prepare suspensions manually, suspension preparation instructions can be found in the VITEK® Systems Product Information.*

- prepared the inocula and have all material positioned by the SCS

Table 6-3: Processing Test Cards (Using the Smart Carrier)

Activity	Reference Section(s)
1) Confirm configuration settings.	• Configuration Options for Smart Carrier Workflow on page 6-16. • Cassette Edit Screen on page 6-11.
2) Insert a cassette to display the Cassette Edit screen.	• Step 1 on page 6-17.
3) Enter information for the first test card and specimen in the first slot: • Using the SCS bar code scanner, *or* • Using the SCS keyboard	• Entering Test Information With SCS on page 6-17. • SCS Functions on page 6-13. • Option Boxes on page 6-14.
4) Place the first test card and specimen test tube in their appropriate slots.	N/A
5) Continue activities 3 and 4, filling the cassette slots sequentially.	

Entering Test Information With SCS

The Cassette Edit screen is used to store information about specimens and their test cards. You enter the information by positioning the cursor in a data field for a particular test card slot. By default, the cursor is always in the **Accession ID** field for slot 1 when the screen is first accessed. All fields are empty unless previous data was entered for that slot.

1) Access the Cassette Edit screen.

The SCS displays the Cassette Edit screen (see Figure 6-7) automatically whenever a cassette is firmly seated on the SCS base unit.

2) Select the correct slot.

- Make sure that the Cassette Edit screen is displaying the correct slot (1–15). Use the **Next Slot** or **Previous Slot** keys.
- Make sure that the cursor (blinking bar) is in the correct field. Use the **Up** or **Down Arrow** keys.

3) Enter the data as shown in Table 6-4.

Table 6-4: Data Entry Methods (Smart Carrier Mode)

Field	Bar Code Method	Keyboard Method
Accession ID	Scan the bar code label on the specimen.	Type the *ID* into the **Accession/Lab ID** field.
Card Type	Scan the bar code label on the card.	Type the *18-digit code* from the bar code label on the test card.
Organism ID (AST card)	Scan an organism ID from the SCS *Job Aid Card.*	Place the cursor in the **Organism ID** field and press the **Help (?)** key. Select an *organism* from the option box.
Offline Test	Scan a test from the SCS *Job Aid Card*.	Place the cursor in the **Offline Test** field and press the **Help (?)** key. Select a *test* from the option box. If the entered card type is ANC, an Offline Test Result screen will be displayed.
Modifier	Scan a modifier from the SCS *Job Aid Card*.	Place the cursor in the **Modifier** field and press the **Help (?)** key. Select a *modifier* from the option box.

Note: *The SCS does not allow you to enter expired cards.*

Note: *If you need to change any of the data you have entered, you must do so before you remove the cassette from the SCS.*

Correct Positioning of AST Cards

If you pre-dilute the inocula for the susceptibility tests, you can place the test cards into any slots in the cassette, in any order you choose. However, when VITEK® 2 is performing the dilution (Automatic Dilution mode), you must follow these rules:

- The AST card must be placed in a slot immediately following the slot containing the inoculum test tube.

- A Gram negative inoculum can be used for either one or two susceptibility tests. When diluting the inocula for two tests, the test cards must occupy the two slots immediately following the slot containing the inoculum test tube.
- The VITEK® 2 AST card type (e.g., AST-P515) MUST be entered in the **Card Type** field on the Smart Carrier Station Cassette Edit screen. The instrument is unable to prepare an AST dilution if the card type is not entered.

These rules apply whether or not an ID card is used.

Loading a Cassette

BIOHAZARD WARNING

The cassette should be considered as potentially contaminated and should be handled appropriately. Qualified laboratory personnel should take the usual precautions necessary for infectious agents.

After the information for a cassette has been entered at the SCS, the cassette is ready to be loaded into the VITEK® 2 instrument. Before you load the cassette, however, you should always check the Status screen. Look at the parameters in Table 6-5 to make sure it is okay to load the cassette.

Table 6-5: Cassette Load Parameters (Smart Carrier Mode)

Parameter	What to Look For
Status	This field should read **OK**.
Available Slots	The value in this field should be greater than or equal to the number of test cards you are loading.
Tips and Saline	The level of both disposables should be greater than or equal to the number of test cards you are loading. ***Note:*** *This parameter may be ignored if you are operating in the Pre-diluted mode.*
Cassette Mode	This field should read SCS (Smart Carrier Station).

Using the Cassette Load Station

The Cassette Load Station is composed of the cassette load door and a green indicator light. The indicator light tells you the status of the load station, as shown in Table 4-2.

Before you attempt to load a cassette, make sure the indicator light is on or is blinking.

Loading a Cassette

1) Open the Cassette Load Station by lifting the cassette load door up. There should be an empty boat at the station, or one with a cassette that contains waste.

CAUTION: Do not attempt to load a cassette if a boat is not at the station. Damage to the cassette and the VITEK® 2 instrument is possible.

2) Place the cassette in the boat so that the specimen test tubes face the front of the instrument.

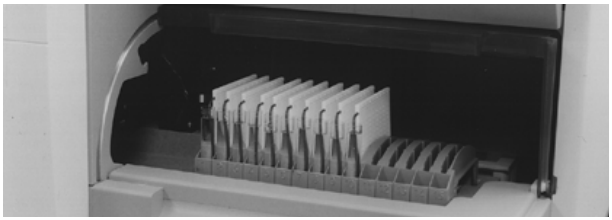


Figure 6-11: Correct Orientation of Cassettes

Note: *The boat is shaped such that it will only accept a cassette in the proper orientation.*

CAUTION: To avoid possible processing errors, make sure that all the test cards and test tubes are properly seated in the cassette.

3) Close the cassette load door.

The **Cassette** icon appears on the Status screen.

4) Monitor the instrument until the **Cassette** icon disappears and the boat moves forward to process cards.

Monitoring Card Processing

After a cassette is loaded, the test cards in it are scanned by the bar code reader in VITEK® 2. This information is sent to the workstation so that you can see a listing of the test cards in the Directory window. Additional

information is provided once the test cards reach the Card Incubator and Reader Station and are read for the first time.

Note: *The VITEK® 2 instrument should be attended during the first minute after a cassette is loaded and the boat moves forward to process cards. This period is denoted by the presence of the* ***Cassette*** *icon on the VITEK® 2 Status screen. See* *Cassette Load Processing Errors on page 8-10* *for additional information.*

Tracking Cassettes and Cards

The **Cassette Name** and **Load Time**, which appear in the VITEK® 2 Directory window at the workstation, help you identify each cassette in the VITEK® 2 instrument. Table 6-6 shows how you can track each test card.

Table 6-6: Card Identity Components (Smart Carrier Mode)

Identifier	Example	Source
Cassette Name	RMT	The Smart Carrier Station into which the cassette was scanned.
Slot position (1–15) of the test card in the cassette.	03	The actual test card position in the cassette as read by the VITEK® 2 bar code reader.
Load Time	Apr 03 08:35:40	The date and time the test card was read by the VITEK® 2 bar code reader.

Processing Test Cards in Cassette Only Mode

Note: *If your system has a Smart Carrier Station, refer to the section* *Processing Test Cards Using the Smart Carrier Station on page 6-16**.*

Configuration Options in Cassette Only Mode

On the VITEK® 2 instrument, set the:

- Cassette Mode to **Cassette Only**
- Dilution Mode to **Automatic** or **Pre-Diluted**, as appropriate

Note: *The procedure for these options appear in* *Chapter 5**.*

Cassette Only Mode Workflow

Table 6-7 provides a generalized workflow for working without a SCS. This workflow assumes that you have:

- selected the VITEK® 2 test cards to process
- decided whether to prepare susceptibility suspensions manually or automatically using VITEK® 2

Note: *If you choose to prepare suspensions manually, suspension preparation instructions can be found in the VITEK® 2 Systems Product Information.*

Table 6-7: Processing Test Cards (Cassette Only Mode)

Activity	Reference(s)
1) Make sure that all configuration options are set correctly.	Configuration Options in Cassette Only Mode on page 6-21.
2) Print a cassette worksheet at the workstation.	From the VITEK® 2 Directory, select: **Cassette>Print Worksheet**.
3) Fill in the cassette worksheet with the test card and specimen information for the cassette.	Using the Cassette Worksheet on page 6-22.
4) Place the test cards and specimen test tubes in their appropriate slots.	Correct Positioning of Susceptibility Test Cards on page 6-24.
5) Access the Cassette Setup function on the VITEK® 2 instrument. Select or enter a *cassette name* and, if necessary, change the dilution mode.	Using the Cassette Setup Function on page 6-24.
6) Load the cassette onto the VITEK® 2 instrument.	Loading a Cassette on page 6-25.
7) Enter the information from the cassette worksheet into the Cassette Edit window. ***Note:*** *During the first minute of processing, a* ***Cassette*** *icon appears on the VITEK® 2 Status screen. Wait until the boat moves forward to process cards before accessing the Cassette Edit window.*	Monitoring Test Card Processing on page 6-27.

Cassette Preparation

Follow these procedures to set up the test cards and specimens for a cassette.

Printing a Cassette Worksheet

Print cassette worksheets at the VITEK® 2 workstation. Refer to the topic Generating Cassette Worksheets in the *VITEK® 2 Software and AES User Manual*.

Using the Cassette Worksheet

The Cassette Worksheet (Figure 6-12) is designed to help you organize a set of test cards and specimens for a cassette.

Date: 07/26/2005 08:38:23 bioMérieux Page: 1
WSVT2-R04.02 Cassette Report

1 Cassette ID: _____

2 Tests: _____

3 Instrument: _____

	4 Test Type	Accession ID	Organism	Modifier	Offline Tests
1	5				
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					

Figure 6-12: Cassette Worksheet

1 — Cassette ID. Fill in the cassette name here.

2 — Tests. Fill in the number of test cards being placed in the cassette.

3 – Instrument Name. Fill in the name of the VITEK® 2 instrument into which you placed the cassette.

4 – Fields. Use these fields to fill in the applicable information about the test cards and specimens.

5 – Slot Numbers. The worksheet is preprinted with the 15 slot numbers.

Correct Positioning of Susceptibility Test Cards

If you pre-dilute the inocula for the susceptibility tests, you can place the test cards into any slots in the cassette, in any order you choose. However, when VITEK® 2 is performing the dilution (Automatic Dilution mode), you must follow these rules:

- The AST card must be placed in a slot immediately following the slot containing the inoculum test tube.
- A Gram negative inoculum can be used for either one or two susceptibility tests. When diluting the inocula for two tests, the test cards must occupy the two slots immediately following the slot containing the inoculum test tube.

These rules apply whether or not an ID card is used.

Using the Cassette Setup Function

Use the Cassette Setup function to define the cassette name to the instrument, and, if necessary, to change the Dilution Mode setting for a cassette.

1) Access the **Cassette Setup** function on the Main Menu.

Note: *If the VITEK® 2 instrument is in Smart Carrier mode, the **Cassette Setup** function cannot be accessed. If you attempt to use the option, the screen displays the following message:*

```
This option is used with Cassette Only mode.
```

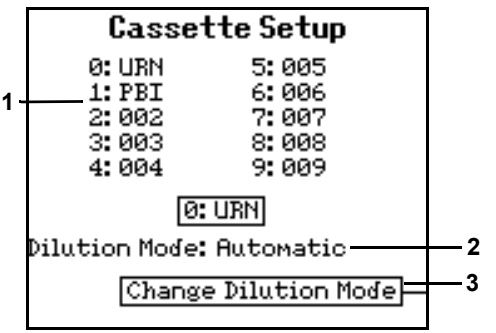


Figure 6-13: Cassette Setup Screen

The screen has places for up to ten cassette names. You do not enter these names on this screen. That is done in the **Cassette Names** function on the **Configuration** menu.

2) Select one of the *cassette names* (**1**, Figure 6-13) from the list shown by pressing its corresponding number on the keypad.

The selected name is highlighted.

Note: *If you need to add a new cassette name, refer to the section Cassette Names on page 5-3.*

3) If necessary, press the **Change Dilution Mode** button (**3**) to change the current dilution mode (**2**).

BIOHAZARD WARNING

Biohazardous spills can occur inside the VITEK® 2 instrument if the Dilution Mode option is not properly set, especially if pre-diluted samples are used with the mode set to Automatic. All organism suspensions should be considered as potentially infectious. Qualified laboratory personnel should use acceptable procedures for biohazardous material.

4) Press **Enter** to accept the information as shown on the screen.

Loading a Cassette

BIOHAZARD WARNING

The cassette should be considered as potentially contaminated and should be handled appropriately. Qualified laboratory personnel should take the usual precautions necessary for infectious agents

Before you load a cassette you should always check the Status screen. Look at the parameters in Table 6-8 to make sure it is okay to load the cassette.

Table 6-8: Cassette Load Parameters (Cassette Only Mode)

Parameter	What to Look For
Status	This field should read **OK**.
MAX Available Slots	The value in this field should be greater than or equal to the number of test cards you are loading.
Available ID Slots **(VITEK® 2 XL only)**	The value in this field should be greater than or equal to the number of identification test cards you are loading.

Table 6-8: Cassette Load Parameters (Cassette Only Mode) (Continued)

Parameter	What to Look For
Tips and Saline	The level of both disposables should be greater than or equal to the number of test cards you are loading. ***Note:*** *This parameter may be ignored if you are operating in the manual dilution mode.*
Cassette Name	The name of the previously used cassette is shown, and will be applied to this cassette unless you change it.
Dilution Mode	Make sure that the mode displayed matches the way in which you are processing the test cards.

Using the Cassette Load Station

The Cassette Load Station is composed of the cassette load door and a green indicator light (illustrated in Chapter 4).

The indicator light tells you the status of the Load Station (Table 4-2).

Before you attempt to load a cassette, make sure the indicator light is on or blinking.

Loading a Cassette

1) Open the Cassette Load Station by lifting the cassette load door up. There should be an empty boat at the station, or one with a cassette that contains waste.

CAUTION: Do not attempt to load a cassette if a boat is not at the station. Damage to the cassette and the VITEK® 2 instrument is possible.

2) Place the cassette in the boat so that the specimen test tubes are towards the front of the instrument.

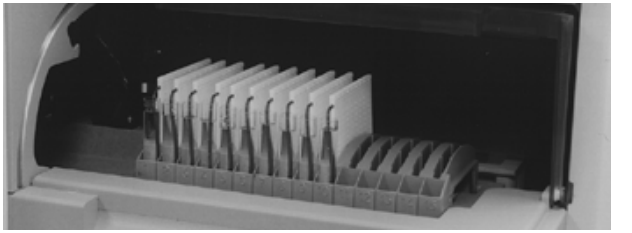


Figure 6-14: Correct Orientation of Cassette

Note: *The boat is shaped such that it will only accept a cassette in the proper orientation.*

3) Close the cassette load door.

The **Cassette** icon appears on the Status screen.

4) Monitor the instrument until the **Cassette** icon disappears and the boat moves forward to process cards.

Monitoring Test Card Processing

After a cassette is loaded, the test cards in it are scanned by the bar code reader in VITEK® 2. This information is sent to the workstation so that you can see a listing of the test cards in the Directory window. Additional information is provided once the test cards reach the Card Incubator and Reader Station and are read for the first time.

Entering Data for a Cassette

During the first minute after you load a cassette, the bar code on each test card is read. From this bar code reading, the instrument knows the number of test cards in the cassette, the type of test cards, and the position of each test card. This information, along with the cassette name you selected in the **Cassette Setup** function, is sent to the workstation.

The information can be viewed in the Cassette Edit window, which is part of the VITEK® 2 workstation software. You can access that screen and, using the Cassette Worksheet, fill in the remaining information for the cassette once the test cards have been loaded into the carousel.

For information on using the Cassette Edit window, please refer to this topic in the *VITEK® 2 Software and AES User Manual*.

Tracking Cassettes and Cards

The **Cassette Name** and **Load Time**, which appear in the VITEK® 2 Directory window at the workstation, help you identify each cassette in the VITEK® 2 instrument. Table 6-9 shows how you can track each test card.

Table 6-9: Card Identity Components (Cassette Only Mode)

Identifier	Example	Source
Cassette Name	RMT	The three-character cassette name that is entered in the **Cassette Name** function.

Table 6-9: Card Identity Components (Cassette Only Mode) (Continued)

Identifier	Example	Source
Slot position (1–15) of the test card in the cassette.	03	The actual test card position in the cassette as read by the VITEK® 2 bar code reader.
Load Time	Apr 03 08:35:40	The date and time the test card was read by the VITEK® 2 bar code reader.

The **Cassette Name** can represent any laboratory parameter you choose, such as a technologist's initials, a specimen source, or a work shift.

Batch Loads (Smart Carrier or Cassette Only Mode)

Selecting Batch Loading

Batches of three or four cassettes can be loaded in rapid succession using the Batch Load function.

Before You Begin

Because a batch load requires most or all of the VITEK® 2 resources, you should do the following before initiating a batch load:

1) Batch loading requires at least three cassettes, so check your work load to make sure that you are processing enough test cards.

2) Check the Status screen to make sure that:

- The number of available slots equals or exceeds the number of test cards that you are loading.
- The quantities of tips and saline is sufficient for the number of test cards that you are loading.

Starting a Batch Load

This process begins with the preparation of the cassettes. Refer to one of the following two procedures:

- Cassette preparation in **Smart Carrier** mode, page 6-16.
- Cassette preparation in **Cassette Only** mode, page 6-22.

Note: *You must prepare all three or four of the cassettes to be included in the batch load before proceeding.*

1) Bring the cassettes to the VITEK® 2 instrument.

2) Access the **Batch Load** function on the Main Menu.

The VITEK® 2 instrument checks to ensure that at least three boats are available, and that there are no test cards currently in the card transport system. It then displays the following screen:

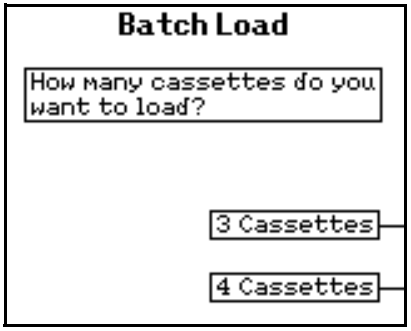


Figure 6-15: Batch Load Screen

Note: *This screen does not appear if there are only three boats in the instrument. In that case, a batch load of three cassettes is assumed.*

If less than three boats are available, or if the card transport system is unavailable, the following message appears:

```
The card transport system is not available for batch
load. Load a single boat or try again later.
```

3) Press the *option button* that corresponds to the number of cassettes that you want to load.

- The following screen displays for Smart Carrier Mode:

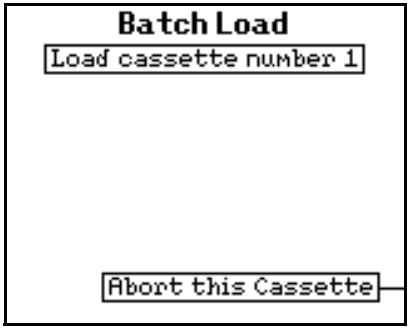


Figure 6-16: Smart Carrier Mode Batch Load Screen

- The following screen displays for Cassette Only Mode:

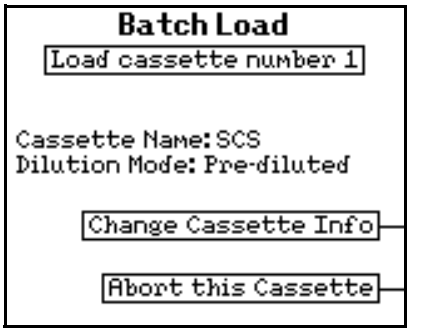


Figure 6-17: Cassette Only Mode Batch Load Screen

4) Open the door to the Load Station, place the cassette in the boat, and close the door.

The instrument moves the boat away from the Load Station, moves the next boat into the station, and redisplays the screen shown in the previous step.

5) Repeat Step 4 as required for the other cassettes.

Unloading the Cassette and Removing Waste

This section describes two procedures that you need to perform on a regular basis. One is to remove empty cassettes from the instrument, which should be done whenever the light at the Cassette Load Station is blinking. The other is to remove ejected test cards, which should be done routinely whenever a new cassette is loaded. Performing these activities ensures that VITEK® 2 can continue to support your laboratory's work load.

Unloading a Cassette

During test card processing, test cards are unloaded from the cassette and placed into the carousel at the Card Reader and Incubator Station. This means that when the boat and cassette return to the unload station, only the specimen test tubes and the severed transfer tubes remain in the cassette. The cassette must be removed so that the boat is available to accept another cassette.

1) When you are processing test cards, look for the green indicator light at the unload station to be blinking.

This indicates that an empty cassette is at the station.

For more information about the indicator light, see the section Using the Cassette Load Station on page 6-19 or on page 6-26.

2) Open the cassette load door and remove the cassette from the boat.

Note: The boat itself should not be removed.

3) Close the cassette load door.

CAUTION: Leaving the door to the Cassette Unload station open will interfere with the proper processing of the test cards in the VITEK® 2 instrument.

4) Dispose of the materials in the cassette. The cassette can now be used to process additional test cards.

BIOHAZARD WARNING

All of the materials in an empty cassette should be treated as biohazards and disposed of accordingly. All organism suspensions should be considered as potentially infectious. Qualified laboratory personnel should use acceptable procedures for biohazardous material.

Removing Ejected Test Cards

When a test card is ejected, it is removed from the carousel in the Card Reader and Incubator Station, and placed in the Waste Collection Station (see Figure 6-18). This station has a capacity of 60 test cards, equivalent to the capacity of the carousel. However, it is recommend that you check and empty the Waste Collection Station every time you load a new cassette.

Note: *Once cards have been removed from the Waste Collection Station, never reinsert them. This will cause the instrument to jam.*

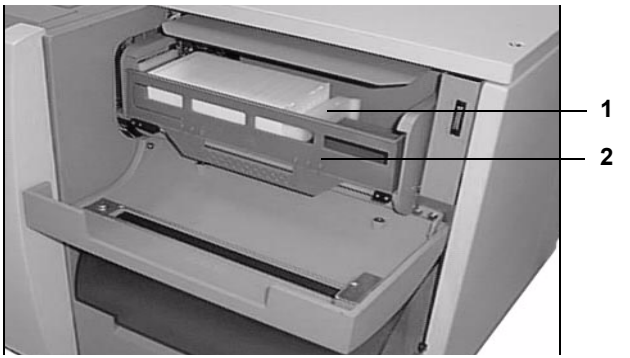


Figure 6-18: The Waste Collection Station

Removing the Waste Collection Tray

1) Open the Waste Collection Station door. Note that waste test cards are held in a removable tray.

2) Place the index finger of one hand on the sliding retainer bar (**1**, Figure 6-18) to prevent it from snapping back.

3) Remove the waste collection tray (**2**) from the station by lifting the front edge of the tray slightly and then pulling it toward you.

4) When the tray is clear of the station, allow the sliding retainer bar to slowly slide back into place.

5) Dispose of the test cards in the tray.

Note: *Once cards have been removed from the Waste Collection Station, never reinsert them. This will cause the instrument to jam.*

BIOHAZARD WARNING

Although VITEK® 2 test cards are sealed, they should be treated as biohazards and disposed of accordingly.

Replacing the Waste Collection Tray

1) Slide the tray onto its shelf, lifting the front edge to clear the retaining brackets.

2) Close the waste collection door.

Note: *If the waste collection tray is not replaced, the instrument cannot eject cards and eventually stops processing.*

MAINTAINING THE VITEK® 2 INSTRUMENT 7

Introduction

This chapter includes the procedures required to maintain the VITEK® 2 instrument. Maintenance includes monitoring and changing the disposables, cleaning the boats and the carousel, and general maintenance and cleaning.

Note: *The Maintenance Log provided at the end of this chapter lists recommended maintenance procedures and their frequency. Please make one copy for your use and keep the original with this manual.*

Note: *Avoid pressing the **Help (?)** key when the instrument is performing maintenance functions. On rare occasions the interface may display a blank screen after reviewing a message during a maintenance function. If that occurs, recycle the power.*

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Maintaining Disposables

Chapter 6 introduced the Status screen and how to incorporate it into your workflow. A specific part of that screen is devoted to the maintenance of the VITEK® 2 disposables.

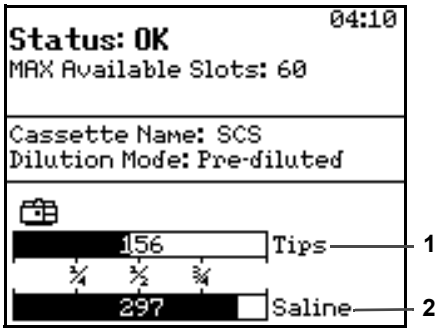

Figure 7-1: VITEK® 2 Status Screen

Monitoring the Disposables

Note the two bar graphs at the bottom of the screen. The Tips graph (**1,** Figure 7-1) displays the current level of pipette tips that remain in the instrument. The Saline graph (**2**) displays the level of saline that remains in the instrument.

Interpreting the Graphs

As the two disposables are used, the shaded portion of the graphs moves to the left. At the same time, the value inside the graph decreases correspondingly. The graphs are marked to show full (330), three-quarter (248), one-half (165), and one-quarter (83) capacity. If the level of either disposable drops below 40, the value changes to **Low**.

What do these numbers mean and how should you use them? The graphs and their values refer specifically to the number of antimicrobial susceptibility tests (AST) that can be processed. This means that the graphs and values are important only when you are processing ASTs in the Automatic Dilution mode, that is, when the VITEK® 2 instrument is performing the dilution of the AST inocula. For example, when one of the graphs is at one-half capacity, it means that enough of that disposable remains to process approximately 160 ASTs.

Using the Graphs

The best way to use the graphs is to periodically compare the levels of the graphs to the number of ASTs you anticipate during a period. If the disposables level is lower than the anticipated work load, install an accessory kit before you begin (see following sections). In this way, your workflow will not be interrupted during test card processing. When comparing the disposables level to your work load, it is important to remember that the graphs are APPROXIMATIONS of the actual level of disposables.

Expiration of Disposables

VITEK® 2 is programmed to measure the amount of time that the disposables have been in the instrument. When the specified time limit is exceeded, VITEK® 2 displays an error message telling you that a disposable has expired.

The Dispenser/Pipettor Accessory Kit

If the disposables have reached a low level, or if they have expired, you need to install a Dispenser/Pipettor Accessory Kit. The kit consists of a container of pipette tips and a saline dispenser tube with its associated tubing. The following two sections in this chapter describe how to install an accessory kit.

Installing an Accessory Kit, Part A: Saline and Tubing

Note: *If the card transport system is processing cassettes through the Card Transport Station, the following message appears:*

```
Card transport system is busy. Please try later.
```

CAUTION*: Use aseptic technique when installing an accessory kit.*

1) Access the Change Saline function using the path:

Main Menu > **Utilities** > **Maintenance** > **Change Saline**

The following prompt appears:

```
About to change saline. Do you wish to continue?
```

2) Press **Yes** to continue with the saline change.

After you proceed the instrument displays the following message:

```
Proceed with saline change?
```

3) Open the front access door (**1**, Figure 7-2) to expose the Dispenser Station, then lift the saline access door (**2**) to expose the saline bag.

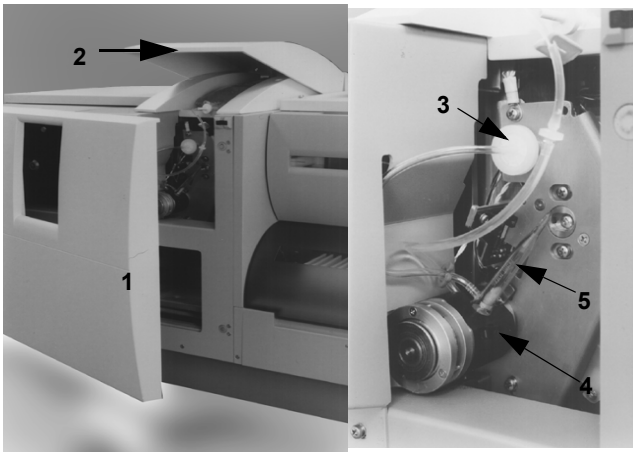

Figure 7-2: Location of Saline Dispensing Chamber

4) Pull on the filter disk (**3**) to remove it from its connector.

5) While pushing the **Dispenser Release** button (**4**), carefully pull the shot tube (**5**) out of its housing.

6) The entire assembly is now disconnected. Since they are Single Use Only items, you must discard the saline tube, its tubing, and the saline bag.

Note: *Since the saline dispenser tube does not come in contact with any specimen, it is not considered a biohazard. Use normal laboratory precautions when disposing of this assembly.*

CAUTION: To prevent possible contamination of the saline, use aseptic technique when handling the saline dispenser tube.

7) Remove a new bag of 0.45% sterile saline from its protective pouch.

8) Remove a new tubing assembly from its container.

9) Remove the covers from the large port of the saline bag and from the cannula of the tubing assembly.

10) Insert the cannula (**6**, Figure 7-3) from the tubing assembly into the port (**7**) of the saline bag.

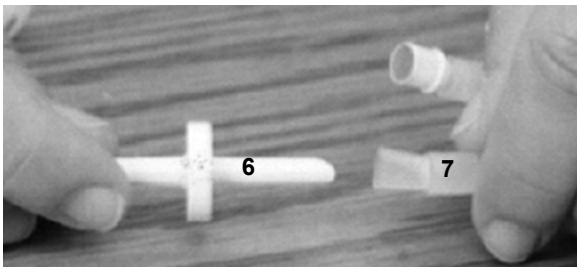

Figure 7-3: Cannula and Tubing Assembly

11) Place the new bag of saline on its shelf on the top of the instrument, placing the eyelet of the bag over the post at the back of the shelf.

12) While pushing the release button (**8**, Figure 7-4), insert the saline dispenser tube (**9**) into its housing. After the tube is fully inserted, release the button.

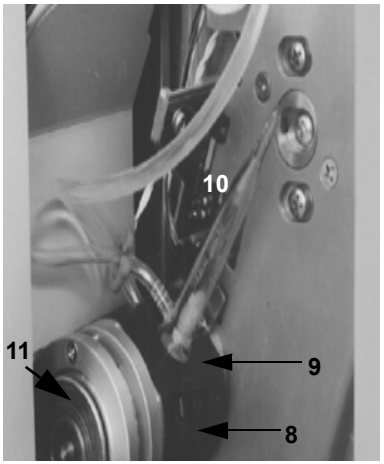

Figure 7-4: Saline Dispensing Chamber

Note: *Make sure that the saline dispenser tube is firmly seated in the housing and that the tubing flows smoothly without any kinks or twisting.*

13) Grasp the filter disk *(***10**) and firmly push it onto the connector located above the saline dispenser tube.

Avoid excessive pressure, however, as it could cause the filter to break.

14) Press the round plate (**11**) to allow saline to flow into the saline dispenser tube. Do not allow the saline level to fill above the top inlet port (**12**, Figure 7-5).

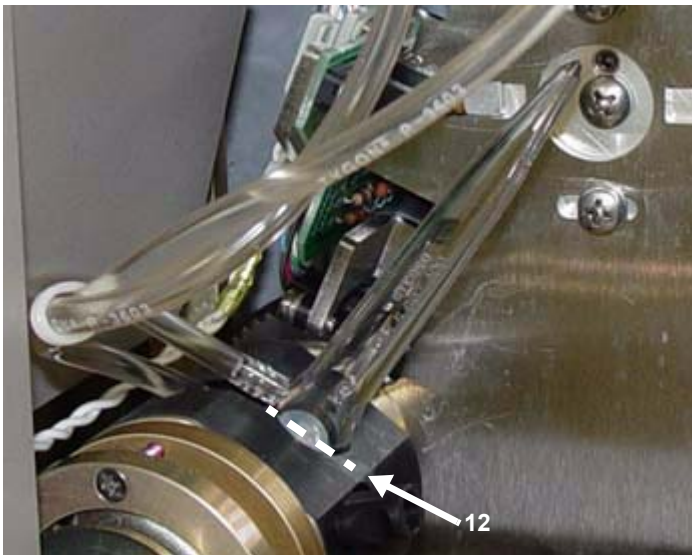

Figure 7-5: Saline Fill Line

15) Release the round plate (**11**, Figure 7-4).

16) Close both the front access door and the saline access door to the instrument.

17) Press **Done**.

The following message appears:

```
Performing Dispenser Self Test
```

The self test checks for proper installation of the saline dispenser tube. It is recommended that you wait for the test to complete (about 20 seconds) before leaving the instrument.

If the test is successful, the Maintenance menu appears.

If the test fails, the following message displays:

```
Saline Dispenser Tube installation error
```

There is a problem with the saline dispenser tube installation. Inspect the tube installation and correct it as needed.

18) Press **Continue** to return to the Change Saline screen.

19) At the Change Saline screen, press **Cancel** to return to the Maintenance menu or **Done** to repeat the test.

20) Perform the Dispenser/Pipettor diagnostic test, described on page 8-21, to ensure that the Dispenser Station is functioning properly.

Installing an Accessory Kit, Part B: Pipette Tips

If the card transport system is processing cassettes through the Card Transport Station, the following message appears:

```
Card Transport System is busy. Please try later.
```

CAUTION: Use aseptic technique when installing an accessory kit.

1) Access the Change Pipette Tips function using the path:

   Main Menu > **Utilities** > **Maintenance** > **Change Pipette Tips**

2) The following message appears:

   ```
   About to change pipette tips. Do you wish to continue?
   ```

3) Press **Yes** to continue with the pipette tip change.

   The following message appears:

   ```
   Proceed with adding pipette tips.
   ```

4) Open the front access door (**1**, Figure 7-2) of VITEK® 2 to expose the Pipettor Station.

5) Open the Pipette Tip access door.

6) Rotate the pipette tip container (**2**, Figure 7-6) 90° in a counterclockwise direction.

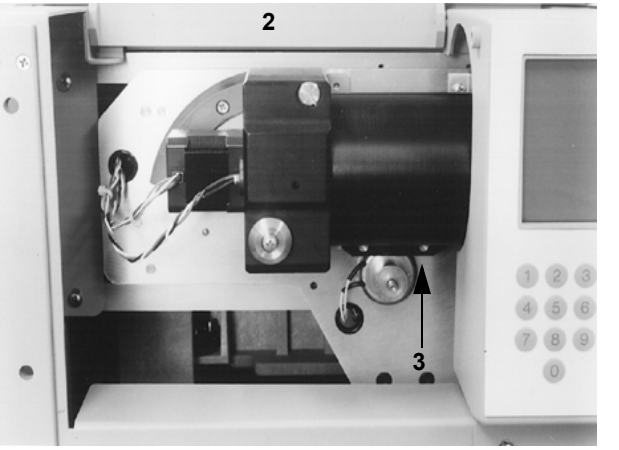

Figure 7-6: Location of Pipettor Tip Container

7) Remove the pipette container from its base using a pulling motion.

8) Discard any pipette tips that remain in the container.

CAUTION: To avoid contaminating new pipette tips, do not touch the inside of the pipette container.

Note: *Discarding the remaining tips is required in order for VITEK® 2 to maintain an accurate count of them. This action also minimizes the risk of contamination.*

9) Open a pipette tip replacement pack and hold it in one hand (see Figure 7-7).

CAUTION: The exposed ends (5, Figure 7-7) of the pipette tips are the ones that come in contact with your specimens. Appropriate precautions to prevent contamination during this procedure are advised.

10) Hold the empty pipette container (**4**) in your other hand with its open end down and lower it over the exposed ends (**5**) of the pipette tips.

11) Invert the container and pack (**6**) so that the pipette tips fall into the container from the pack.

12) Replace the pipette tip container on its base, making sure that it is firmly seated.

There is a key pin on the side of the container that must mate with a slot on the container base.

Note: *If the container is not seated correctly, you will not be able to rotate it back into position.*

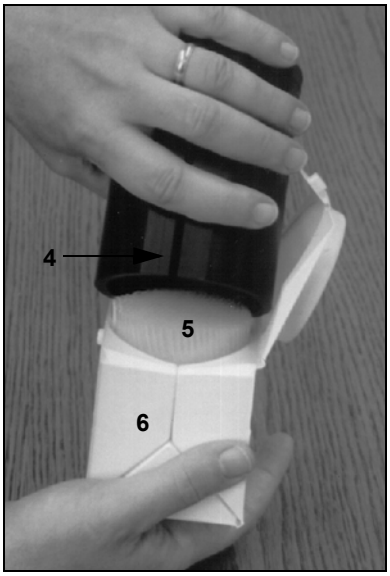

Figure 7-7: Pipette Tip Replacement

13) Rotate the container 90° in a clockwise direction, making sure that it is fully seated in the down position.

14) Close both access doors and press **Done**.

The following message appears:

```
Performing Pipettor Self Test
```

The Pipettor self test only checks the electric motors in the Pipettor Station. If the motors pass the test, no further message is displayed, and you are done with the installation.

If a problem is found, the following message appears:

```
Pipette Tip installation error
```

When this message appears, call bioMérieux for assistance.

15) Perform the Dispenser/Pipettor diagnostic test, described on page 8-20, to ensure that the Pipettor Station is functioning properly.

Cleaning the Carousel

The four sections of a carousel should be removed and cleaned monthly, or as conditions require.

Removing the Carousel for Cleaning

BIOHAZARD WARNING

The carousel should be considered as potentially contaminated and should be handled appropriately. Qualified laboratory personnel should take the usual precautions necessary for infectious agents.

Note: *This procedure must be performed when the VITEK® 2 instrument is completely idle (no cards are processing anywhere in the instrument).*

1) Access the Carousel Cleaning function using the path:

Main Menu > **Utilities** > **Maintenance** > **Cleaning** > **Carousel Cleaning**

Note: *If there are cards processing anywhere in the instrument, a screen prompts you to make sure processing is complete and all cards have been ejected from the instrument before cleaning.*

If you have a VITEK® 2 XL, the screen in Figure 7-8 displays allowing you to select a Reader.

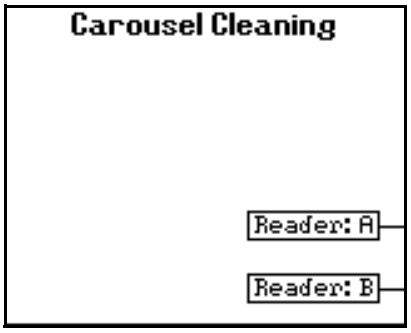

Figure 7-8: VITEK® 2 XL Carousel Cleaning Screen

If cards are not processing in the selected incubator, and the carousel sections have not been removed, the following screen displays:

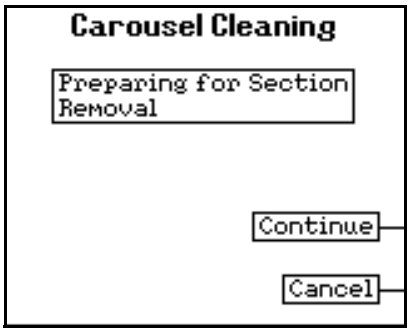

Figure 7-9: VITEK® 2 XL Preparing for Section Removal Screen

Note: *When the **Continue** button is pressed, you are required to remove all of the sections. This will require about four minutes. The **Cancel** button provided here is the only opportunity to cancel this operation.*

2) Press **Continue**.

The following message displays:

`Remove the incubator access cover now`

3) Open the Waste Collection door for the carousel being cleaned.

4) Open the top access door for the carousel being cleaned.

Note: *The remaining steps may be easier if you also remove the Waste Collection tray.*

Note: *There are two types of incubator access covers for the VITEK® 2 instrument. Perform the first part of Step 5 if the machined incubator access cover is in use. Perform the second part of Step 5 if the molded incubator access cover is in use.*

5) Remove the incubator access cover (**1**, Figure 7-10) from the carousel by holding the retaining pin (**2**) on the top of the cover to the right while pulling the cover slightly forward and to the right, out of the instrument.

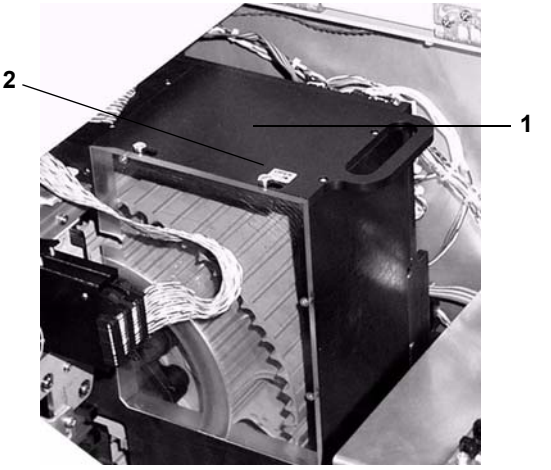

Figure 7-10: Machined Incubator Access Cover

or

Remove the incubator access cover (**3**, Figure 7-11) from the carousel by lifting the top of the cover straight up from the instrument.

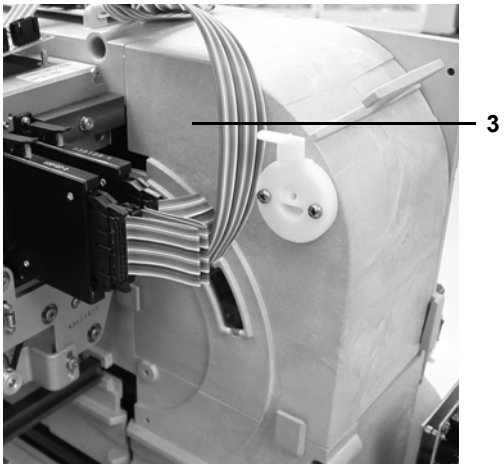

Figure 7-11: Molded Incubator Access Cover

When you remove the cover, the message on the screen changes to:

`Preparing for Section Removal`

6) When the carousel is in position, the following screen displays:

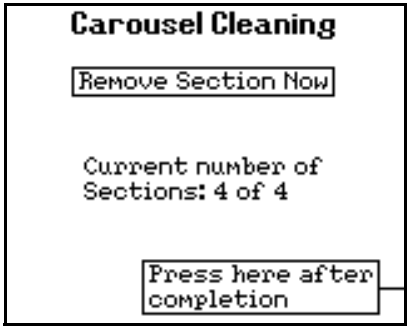

Figure 7-12: Carousel Cleaning Prompt

7) The carousel is removed in four sections. Grasp the first carousel section and pull it slightly forward (toward the front of the instrument). You should then be able to pull the section up and to the right, as shown in Figure 7-13.

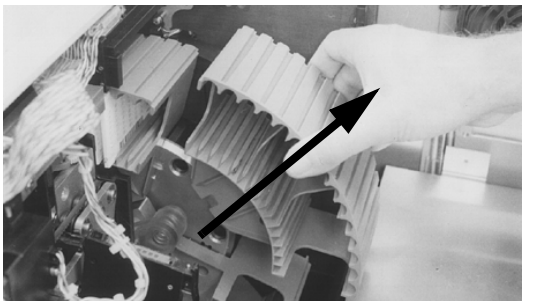

Figure 7-13: Removing a Carousel Section

8) Press the **Press here after completion** option button to indicate removal of the carousel section.

The following message displays:

```
Current number of sections: 3 of 4
```

The carousel turns 90° so that the next section can be removed. During this time the message `Preparing for Section Removal` displays again on the screen.

9) Repeat this procedure, starting at Step 6, until all four carousel sections have been removed.

10) Press the **Press here after completion** option button.

The following message displays:

```
Replace the incubator access cover now
```

Note: *There are two types of incubator access covers for the VITEK® 2 instrument. Perform the first part of Step 11 if the machined incubator access cover is in use. Perform the second part of Step 11 if the molded incubator access cover is in use.*

11) Hold the retaining pin on the top of the cover to the right and carefully replace the incubator access cover over the carousel. Release the retaining pin when the cover is in place.

or

Install the carousel cover over the carousel.

Once you have replaced the incubator access cover, the **Cleaning** menu appears.

For instructions on replacing the carousel, see the procedure Replacing the Carousel After Cleaning on page 7-15.

Carousel Cleaning Methods

The four sections of the carousel should be thoroughly cleaned and dried before they are replaced in the VITEK® 2 instrument. The carousel material is designed to withstand any of the following cleaning methods:

- Automatic dishwasher with standard laboratory detergent

CAUTION: Dishwasher temperatures during the washing and drying cycles must not exceed 85 °C (185 °F). Exceeding this temperature will cause damage to the carousel sections. Use the top rack of the dishwasher.

- 10% bleach solution
- Phenolic cleaning solution

Note: *To disinfect a contaminated surface, use the 10% bleach solution and allow it to remain in contact with the contaminated surface for five minutes.*

Replacing the Carousel After Cleaning

After the four carousel sections have been removed, the **Cleaning** menu displays.

1) Access the **Carousel Cleaning** function using the path:

VITEK 2 Main Menu > Utilities > Maintenance > Cleaning > **Carousel Cleaning**

The following screen message displays:

```
Preparing for Section Replacement
```

Note: *If the power has cycled, the screen below displays automatically.*

2) Press **Continue** to continue with the carousel replacement.

The following message displays:

```
Remove the incubator access cover now
```

Note: *There are two types of incubator access covers for the VITEK® 2 instrument. Perform the first part of Step 3 if the machined incubator access cover is in use. Perform the second part of Step 3 if the molded incubator access cover is in use.*

3) Remove the incubator access cover (**1**, Figure 7-14) from the carousel by holding the retaining pin (**2**) on the top of the cover to the right while pulling the cover slightly forward and to the right, out of the instrument.

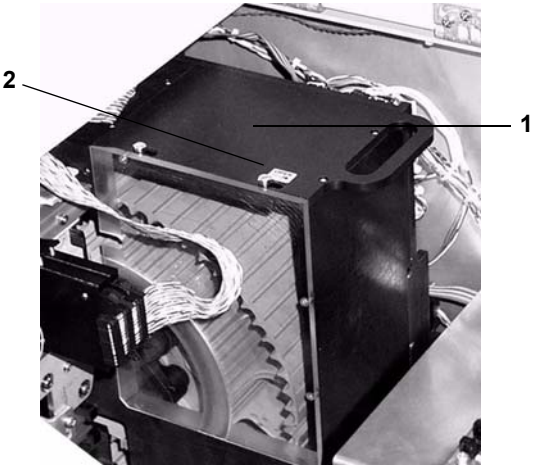

Figure 7-14: Machined Incubator Access Cover

or

Remove the incubator acces cover (**3**, Figure 7-15) from the carousel by lifting the top of the cover straight up from the instrument.

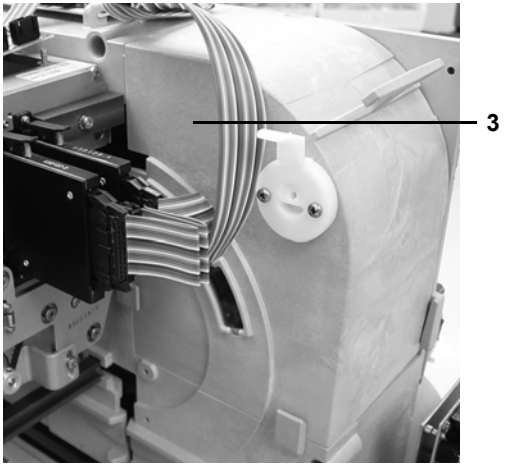

Figure 7-15: Molded Incubator Access Cover

When the access cover has been removed, the following message displays:

```
Preparing for section replacement
```

When the carousel is in position, the following screen displays:

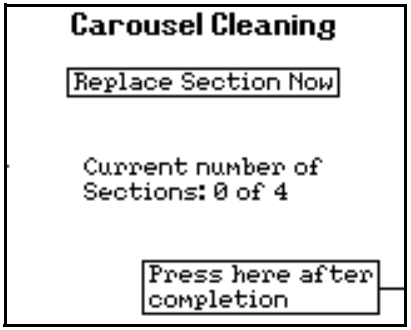

Figure 7-16: Carousel Cleaning Replace Section Now Screen

4) Take any one of the carousel sections and orient it as shown in Figure 7-17. The bottom of the section should be touching the base plate (**3**, Figure 7-17), and the top portion should be tilted slightly toward the front of the instrument.

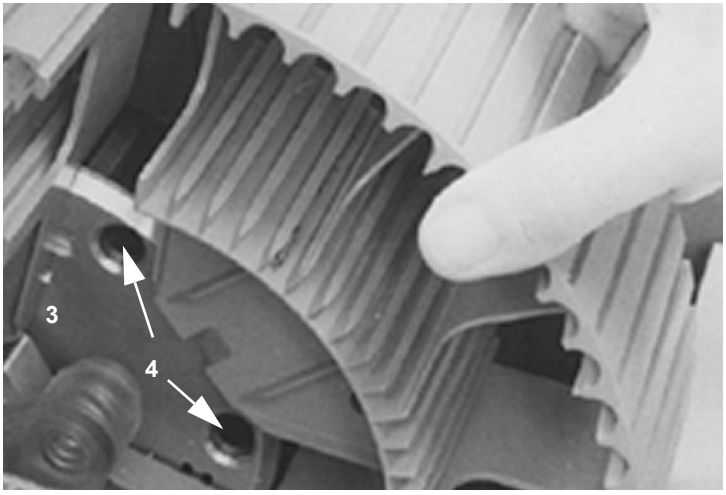

Figure 7-17: Orientation of the Carousel

5) Slide the section down along the base plate while maintaining the tilted angle.

6) When the section has been pushed down all the way, release the top portion, allowing it to rest against the base plate.

When you perform Step 6, two pins on the back of the section should engage the two holes (**4**) in the base plate and secure the section.

7) Press the **Press here after completion** option button to indicate that the section is in place.

The carousel turns 90° to move the first section out of the way and the following message appears:

```
Preparing for Section Replacement
```

8) Repeat this procedure, starting at Step 4, until all four carousel sections have been replaced.

The screen displays the following message:

```
Replace the incubator access cover now
```

Note: *There are two types of incubator access covers for the VITEK® 2 instrument. Perform the first part of Step 9 if the machined incubator access cover is in use. Perform the second part of Step 9 if the molded incubator access cover is in use.*

9) Hold the retaining pin on the top of the cover to the right and carefully replace the incubator access cover over the carousel. Release the retaining pin when the cover is in place.

or

Install the carousel cover over the carousel.

10) Lower the top access door for the carousel being cleaned.

Note: Replace the Waste Collection Tray if it was removed earlier.

11) Close the Waste Collection door.

Cleaning the Cassettes

Cassettes should be cleaned monthly, or as conditions require.

BIOHAZARD WARNING

The cassettes should be considered as potentially contaminated and should be handled appropriately. Qualified laboratory personnel should take the usual precautions necessary for infectious agents.

CAUTION: Exposing the button memory to the recommended cassette cleaning procedures can cause irreparable damage to the unit.

The cassette material is designed to withstand any of the following cleaning methods:

- Automatic dishwasher with standard laboratory detergent

CAUTION: Dishwasher temperatures during the washing and drying cycles must not exceed 85 °C (185 °F). Exceeding this temperature will cause damage to the cassettes. Use the top rack of the dishwasher.

- 10% bleach solution
- Phenolic cleaning solution

Note: *To disinfect a contaminated surface, use the 10% bleach solution and allow it to remain in contact with the contaminated surface for five minutes.*

1) Turn an empty cassette over so that its underside is facing you, as shown in Figure 7-18.

2) Apply a slight inward pressure to the plastic tab (**1**, Figure 7-18) that extends from the memory module (**2**).

3) At the same time, pull the button memory module away from the cassette.

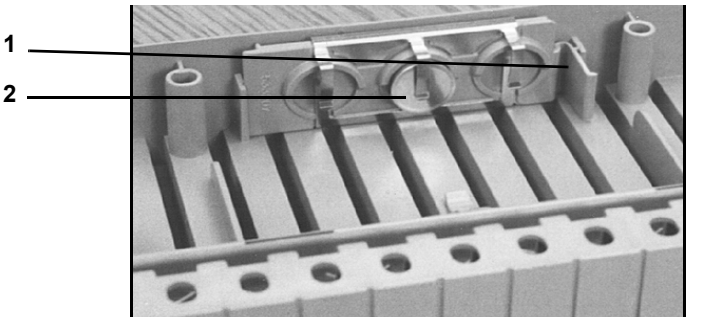

Figure 7-18: Removing the Button Memory Module

4) Clean the metal contacts (**3,** Figure 7-19) on the module with an alcohol wipe.

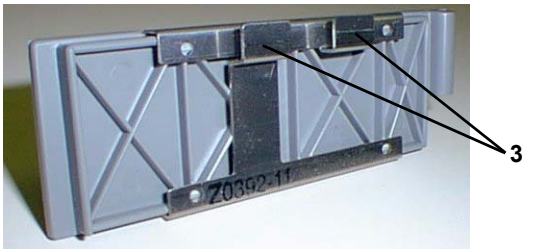

Figure 7-19: Metal Contacts on Cassette

Note: *When cleaning multiple cassettes, it is not necessary to match a button memory module to a particular cassette. The units are completely interchangeable.*

5) The cassettes should be thoroughly cleaned and dried before they are used again.

Replacing the Button Memory Module

1) Turn the cassette over and hold it in your right hand.

2) Hold the memory module by the extended tab (**1**, Figure 7-20) in your right hand so that the two metal contacts (**2**) will line up with the two holes in the side of the cassette (**3**).

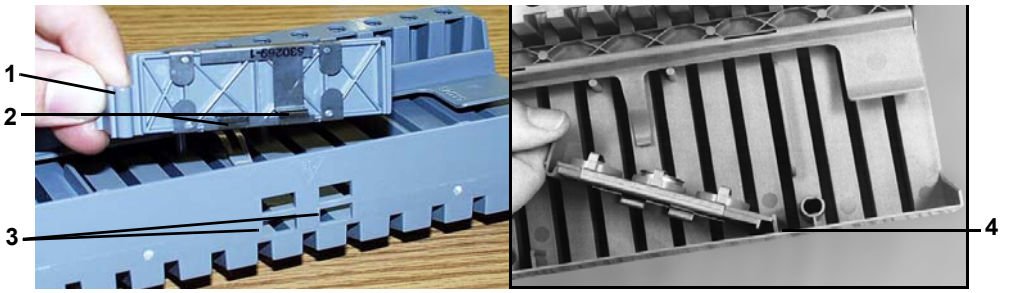

Figure 7-20: Replacing the Button Memory Module

3) Place the other end of the module against the holding bracket (**4**) and push the module towards the side of the cassette.

The module should snap into place.

Cleaning the Boats

Note: *The procedures in this section should be performed monthly, or as conditions require.*

Note: *Do not replace the boats if you are going to clean the inside of the instrument using the procedures that begin on page 7-24.*

Removing Boats for Cleaning

BIOHAZARD WARNING

The boats should be considered as potentially contaminated and should be handled appropriately. Qualified laboratory personnel should take the usual precautions necessary for infectious agents.

Note: *This procedure should be performed while the instrument is idle. If you are performing this procedure to remove only a particular boat, the system can continue to process with as few as one boat.*

1) Access the Boat Cleaning function using the path:

Main Menu > **Utilities** > **Maintenance** > **Cleaning** > **Boat Cleaning**

The following screen appears:

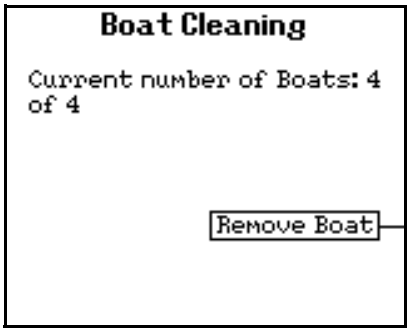

Figure 7-21: Boat Cleaning Prompt

2) Press **Remove Boat**. If there are boats in the card transport system, and it is not idle, the instrument displays the message:

`Card transport system is busy. Please try later.`

If the system is idle, the instrument moves a boat to the boat dock while displaying this message:

`Moving Boat to Boat Dock.`

When the boat is ready for removal, the following message appears:

`Boat is at Boat Dock. Please remove it.`

3) Open the front access door.

A boat will be positioned below the Dispenser/Pipettor Station.

Note: *A boat may be positioned at the Cassette Load Station, but it must NOT be removed from that position.*

4) Remove the boat from below the Dispenser/Pipettor Station and press the **Press here after completion** option button (see Step 2 on page 7-22).

The screen displays:

`Current Number of Boats: 3 of 4.`

5) Repeat this procedure, starting at Step 2, until all 4 boats have been removed.

6) Press the **Previous Screen** key.

Cleaning the Boats

The four boats should be thoroughly cleaned and dried before they are replaced in the VITEK® 2 instrument. The boat material is designed to withstand any of the following cleaning methods.

- Automatic dishwasher with standard laboratory detergent

CAUTION: Dishwasher temperatures during the washing and drying cycles must not exceed 85° C (185° F). Exceeding this temperature will cause damage to the boats. Use the top rack of the dishwasher.

- 10% bleach solution
- Phenolic cleaning solution

Note: *To disinfect a contaminated surface, use the 10% bleach solution and allow it to remain in contact with the contaminated surface for five minutes.*

Replacing Boats after Cleaning

Note: *If you are performing monthly maintenance on the entire instrument, do not replace the boats until after you clean the base pan. Refer to the procedure on page 7-28.*

1) Access the Boat Cleaning function using the path:

Main Menu > **Utilities** > **Maintenance** > **Cleaning** > **Boat Cleaning**

The following message appears:

```
Current number of boats: 0 of 4
```

2) Press **Replace Boat**. If there are boats in the card transport system, and it is not idle, the instrument displays the message:

```
Card transport system is busy. Please try later.
```

3) If the system is idle, the instrument prepares for the boat replacement, and then displays this message:

```
Replace Boat.
```

4) Open the front access door and replace the boat below the Pipettor Station.

Note: *Boats must NOT be replaced at the Cassette Load/Unload Station.*

5) Make sure that:

- The front legs (**1**, Figure 7-22) of the boat are positioned in the channel of the base pan.
- The boat is oriented with the arrow (**2**) pointing toward the back.

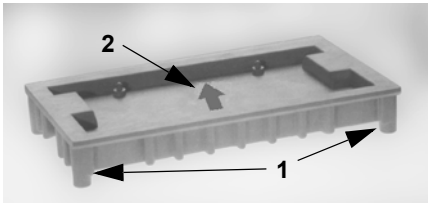

Figure 7-22: Positioning of Boat

6) Press the **Press here after completion** option button shown below after replacing the boat.

The first screen reappears with the boat count at `1 of 4`.

7) Repeat this procedure, starting at Step 2, until all four boats have been replaced.

8) Press the **Previous Screen** key when the display shows:

`Current number of Boats: 4 of 4.`

Cleaning the Instrument Interior

This section describes the procedure for cleaning the inside of the instrument, when the instrument has been shut down and no cards are processing.

To troubleshoot optics while cards are processing, see Cleaning Optics (Cards Processing) on page 8-23.

The procedures in this section should be performed monthly, or as conditions require.

BIOHAZARD WARNING

All organism suspensions should be considered as potentially infectious. Qualified laboratory personnel should use acceptable procedures for biohazardous material.

CAUTION: There are elevated temperatures and hot surfaces inside the instrument. Shut down the instrument before starting the cleaning or any other procedures inside the instrument.

Shutting Down the Instrument

Note: *Finish processing all cards before beginning this procedure.*

1) Access the **Shut Down** function using the path:

Main Menu > **Utilities** > **Maintenance** > **Shut Down**

If any cards are processing the instrument displays this message:

```
Cards are currently processing. Do you wish to
continue?
```

CAUTION: If you select Yes to continue with shutting down the instrument, the cards being processed may be TERMINATED.

The instrument displays the following prompt:

```
Shutting down instrument. Do you wish to continue?
```

2) Press **Yes** to shut down the instrument.

The instrument briefly displays the following message while it moves some internal components to their shutdown positions:

```
Shutting Down Instrument
```

When this process is complete, the instrument displays the message:

```
Shut down has completed. Turn power off when ready.
```

3) Press the AC power switch to shut the instrument off.

4) Remove the AC power cord to prevent any possible electrical hazard.

It is now safe to access the inside of the instrument.

Cleaning the Test Card Collection Tray

1) Open the Waste Collection door and remove the test card collection tray.

2) Thoroughly clean and dry the tray before replacing it in the VITEK® 2 instrument.

The tray material is designed to withstand any of the following cleaning methods:

- Automatic dishwasher with standard laboratory detergent

CAUTION: Dishwasher temperatures during the washing and drying cycles must not exceed 85 °C (185 °F). Exceeding this temperature will cause damage to the cassettes. Use the top rack of the dishwasher.

- 10% bleach solution
- Phenolic cleaning solution

Note: *To disinfect a contaminated surface, use the 10% bleach solution and allow it to remain in contact with the contaminated surface for five minutes.*

3) Replace the test card collection tray in the Waste Collection Station.

Cleaning Optics (Normal Maintenance)

Note: *Perform the procedure Shutting Down the Instrument on page 7-25 before cleaning the optics.*

CAUTION: Do not wear powdered latex gloves while cleaning the optics. The gloves that contain a powder can interfere with the optics.

CAUTION: Do not use commercial glass cleaner when cleaning the optics. This may result in calibration failures observed as the optics age. Clean optics using a quality, lint free lens paper that has been slightly moistened with alcohol.

1) Open the Waste Collection door.

2) Lift the top access door.

This exposes the transmittance (**1**, Figure 7-23) optics.

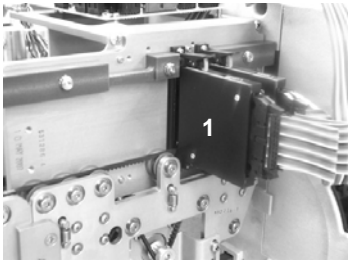

Figure 7-23: Optics

The optics consist of multiple units that are hinged on the bottom and held in place by spring-loaded levers.

3) Using your right hand, grasp the optics unit and place your thumb on the lever (**2**, Figure 7-24).

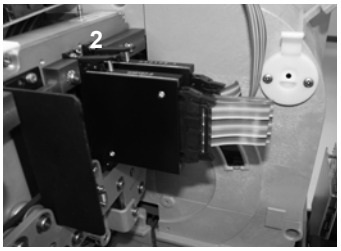

Figure 7-24: Opening the Optics

4) Push down on the lever to release the unit and allow it to rotate on its hinges.

5) Inspect the glass on both surfaces for cracks or scratches.

Note: *Any apparent crack or scratch should be reported to bioMérieux.*

6) Using a quality, lint free lens paper that has been slightly moistened with alcohol, clean both glass surfaces of each Transmittance Optics.

7) While cleaning the emitter side of the Transmittance Optics, push the reader head plate down and clean the glass as close to the belt as possible.

If foreign material remains on either surface, repeat this step using an alcohol wipe. Squeeze out excess alcohol before using, and dry the surface with lens paper. Make sure that you do not leave streaks on the glass.

8) Rotate the unit back into place while pushing down slightly on the lever until it is secured.

9) Replace the empty test card collection tray in the Waste Collection Station.

10) Close the top access door.

11) Close the Waste Collection door.

Note: *After cleaning the optics and returning power to the instrument, perform the Optical Diagnostic Test on page 8-26.*

If you are not performing the remaining cleaning procedures in this section, skip to the procedure Turning the Instrument On on page 7-31.

Cleaning the Base Pan, Vacuum Seal and Vacuum Chamber

Note: *Perform the instrument shutdown procedure on page 7-25 before proceeding with this procedure.*

Note: *If the boats have not already been removed, perform the procedure to remove them. (See page 7-21.)*

BIOHAZARD WARNING

The base pan should not be cleaned unless the drip pan is properly installed. See Cleaning the Drip Pan on page 7-29 for instructions on cleaning the drip pan.

The base pan, vacuum seal, and vacuum chamber are designed to withstand any of the following cleaning methods.

- 10% bleach solution
- Phenolic cleaning solution

Note: *Remove all boats (see Removing Boats for Cleaning on page 7-21) and shut down the instrument (see Shutting Down the Instrument on page 7-25) before performing this procedure.*

The base pan is the surface on which the boats move. The vacuum seal is the bottom surface of the vacuum chamber where the chamber makes contact with a boat (**1**, Figure 7-25).

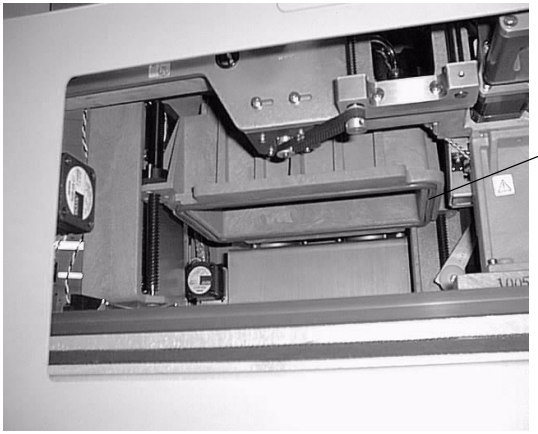

Figure 7-25: Vacuum Seal

1) Using a solution of disinfectant and warm water, wipe off any dust or dirt from the surface of the base pan.

Particular attention should be paid to the area beneath the Dispenser/ Pipettor Station, where drips or spills may have occurred.

Note: *To disinfect a contaminated surface, use the 10% bleach solution and allow it to remain in contact with the contaminated surface for five minutes.*

2) Using plain water, wipe the same surfaces again to remove any disinfectant residue.

3) Repeat Step 1 and Step 2 to clean the vacuum seal and the interior surface of the vacuum chamber.

Note: *The remaining cleaning procedures in this section do not require that the instrument be shut down. You can now turn the instrument back on. See* *Turning the Instrument On on page 7-31*.

Cleaning the Drip Pan

BIOHAZARD WARNING

All organism suspensions should be considered as potentially infectious. Qualified laboratory personnel should use acceptable procedures for biohazardous material.

Note: *This procedure should be performed monthly, or as conditions require.*

VITEK® 2 has a small container, called the drip pan, located underneath the Dispenser/Pipettor Station. The pan is designed to catch any spills that occur at this station.

Note: *This procedure should be performed after you clean the base pan.* *See Cleaning the Base Pan, Vacuum Seal and Vacuum Chamber on page 7-28.*

Removing the Drip Pan

BIOHAZARD WARNING

The contents of the drip pan may include biohazardous materials. Take appropriate precautions.

1) Lower the bottom access door located in the bottom, front portion of the instrument.

The plate is held magnetically and should swing down on its hinges when you pull on it at both ends.

2) Grasp the handle of the drip pan (**1**, Figure 7-26) and carefully pull it from the instrument.

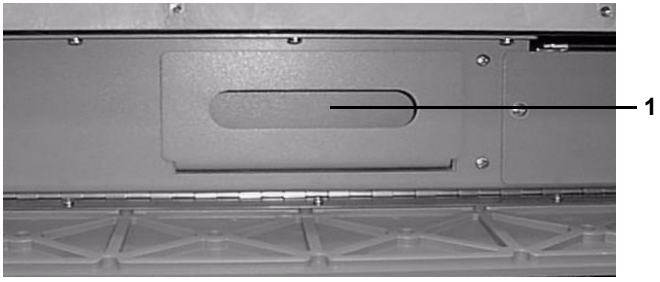

Figure 7-26: Drip Pan Handle

Cleaning the Drip Pan

The drip pan should be thoroughly cleaned and dried before it is replaced in the VITEK® 2 instrument. The pan material is designed to withstand any of the following cleaning methods:

- Automatic dishwasher with standard laboratory detergent

CAUTION: Dishwasher temperatures during the washing and drying cycles must not exceed 85 °C (185 °F). Exceeding this temperature will cause damage to the drip pan. Use the top rack of the dishwasher.

- 10% bleach solution
- Phenolic cleaning solution

Note: *To disinfect a contaminated surface, use the 10% bleach solution and allow it to remain in contact with the contaminated surface for five minutes.*

Replacing the Drip Pan

1) Holding the pan by its handle, push it into the space provided for it under the front of the instrument.

2) Close the bottom access door by pushing it up.

The door is held in place magnetically.

Turning the Instrument On

1) Move the AC power switch to the ON position.

The system goes through the initialization process. When the Status screen appears it will display a status of Cleaning, indicating that all four boats have been removed.

2) Perform the boat replacement procedure that begins on page 7-23.

After all four boats have been replaced, the Status screen should display a status of **OK**.

Note: *If the instrument was shut down for a long period of time, the status may be Warming. Wait until the status is OK before resuming test card processing.*

Cleaning the SCS

BIOHAZARD WARNING

All organism suspensions should be considered as potentially infectious. Qualified laboratory personnel should use acceptable procedures for biohazardous material.

Note: *This procedure should be performed monthly, or as conditions require.*

The SCS base unit, keypad, display, and bar code scanner (except the clear lens) are designed to withstand any of the following cleaning solutions when applied first to a cleaning cloth and then to the SCS:

- 10% bleach solution
- Phenolic cleaning solution

To clean the SCS:

1) Remove the cassette if one is on the SCS base unit.

2) Push the power switch on the SCS to the off position.

3) Remove the SCS AC power cord from its outlet.

4) Note the metal contacts (**1**, Figure 7-27), and take care only to wipe them gently in an up and down motion.

CAUTION: To prevent damage to the metal contacts on the SCS base unit, make sure that you wipe them GENTLY in an up and down motion, rather than side to side.

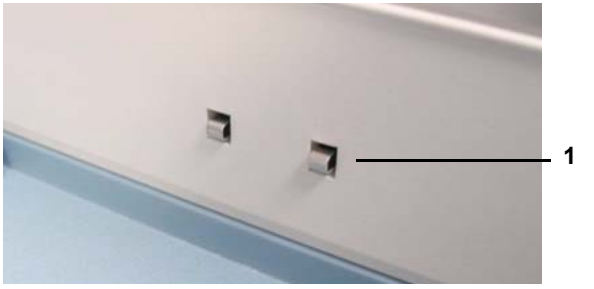

Figure 7-27: SCS Base Unit Metal Contacts

5) Clean all surfaces of the SCS base unit, keypad, display, and bar code scanner, except the clear lens of the scanner.

6) Wipe the clear lens of the bar code scanner using a quality, lint free lens paper that has been moistened with a commercial glass cleaner. If foreign material remains on the surface, repeat this step using an alcohol wipe.

7) Allow all parts to dry thoroughly before reconnecting the power cord and switching the power on.

The VITEK® 2 and VITEK® 2 XL Maintenance Logs on the following pages list recommended maintenance procedures and their frequency. Make one copy for your use and keep the original in this manual.

VITEK® 2 Maintenance Log

Month_____Year_____

Day of Month:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Change Saline A/R																
Change Pipette Tips A/R																
Clean Boats*																
Clean Carousel*																
Clean Cassettes*																
Clean Optics*																
Clean Waste Tray*																
Clean Base Pan*																
Clean Vacuum Seal*																
Clean Vacuum Chamber*																
Clean Drip Pan*																
Check Instrument QC Status Report for the Carousel Temperature** Optics Systems**																
Clean Smart Carrier*																

*** = Monthly** **** = Daily** **A/R = As Required**

MASTER COPY
Make additional copies for your own use.

VITEK® 2 Maintenance Log

Month_____Year_____

Day of Month:	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Change Saline A/R																
Change Pipette Tips A/R																
Clean Boats*																
Clean Carousel*																
Clean Cassettes*																
Clean Optics*																
Clean Waste Tray*																
Clean Base Pan*																
Clean Vacuum Seal*																
Clean Vacuum Chamber*																
Clean Drip Pan*																
Check Instrument QC Status Report for the Carousel Temp.* Optics System*																
Clean Smart Carrier*																

*** = Monthly** **** = Daily** **A/R = As Required**

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VITEK® 2 XL Maintenance Log

Month_____Year_____

Day of Month:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Change Saline A/R																
Change Pipette Tips A/R																
Clean Boats*																
Clean Carousel A & B*																
Clean Cassettes*																
Clean Optics A & B*																
Clean Waste Tray A & B*																
Clean Base Pan*																
Clean Vacuum Seal*																
Clean Vacuum Chamber*																
Clean Drip Pan*																
Check Instrument QC Status Report for the Carousel Temp. A & B** Optics Systems A & B**																
Clean Smart Carrier*																

*** = Monthly** **** = Daily** **A/R = As Required**

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VITEK® 2 XL Maintenance Log

Month_____Year_____

Day of Month:	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Change Saline A/R																
Change Pipette Tips A/R																
Clean Boats*																
Clean Carousel A & B*																
Clean Cassettes*																
Clean Optics A & B*																
Clean Waste Tray A & B*																
Clean Base Pan*																
Clean Vacuum Seal*																
Clean Vacuum Chamber *																
Clean Drip Pan*																
Check Instrument QC Status Report for the Carousel Temp. A & B** Optics Systems A & B**																
Clean Smart Carrier*																

*** = Monthly** **** = Daily** **A/R = As Required**

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TROUBLESHOOTING THE VITEK® 2 INSTRUMENT 8

Introduction

This chapter helps you to resolve any problems that may occur while operating the VITEK® 2 instrument. The first section, Error Handling System, explains how the instrument reacts to an error, and how you, the user, should respond. The second section, Status Screen Error Conditions, covers the Instrument Halted screen, Message Status screen, and Error Status screen. The third section, Cassette Load Processing Errors, covers a specific set of errors that are the ones most likely to occur in normal operation. Other sections cover the Bar Code Reader, and instrument diagnostics and quality control status.

Error Messages and Recovery Procedures

This section contains a listing of all the possible error messages that could occur on the VITEK® 2 instrument and the SCS. This is the first place you should go if an error occurs and you need to find out what to do.

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- *Types of Errors • 8-4*

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Error Handling System

The VITEK® 2 instrument continually monitors itself to ensure that it is operating within specifications. To do this it uses numerous optical, mechanical, and temperature sensors, located within each subsystem. If a sensor detects a problem, the VITEK® 2 instrument is programmed to alert you to the situation, and to provide you with the information you need to resolve the problem. We refer to this process as the Error Handling System. Figure 8-1 illustrates these elements.

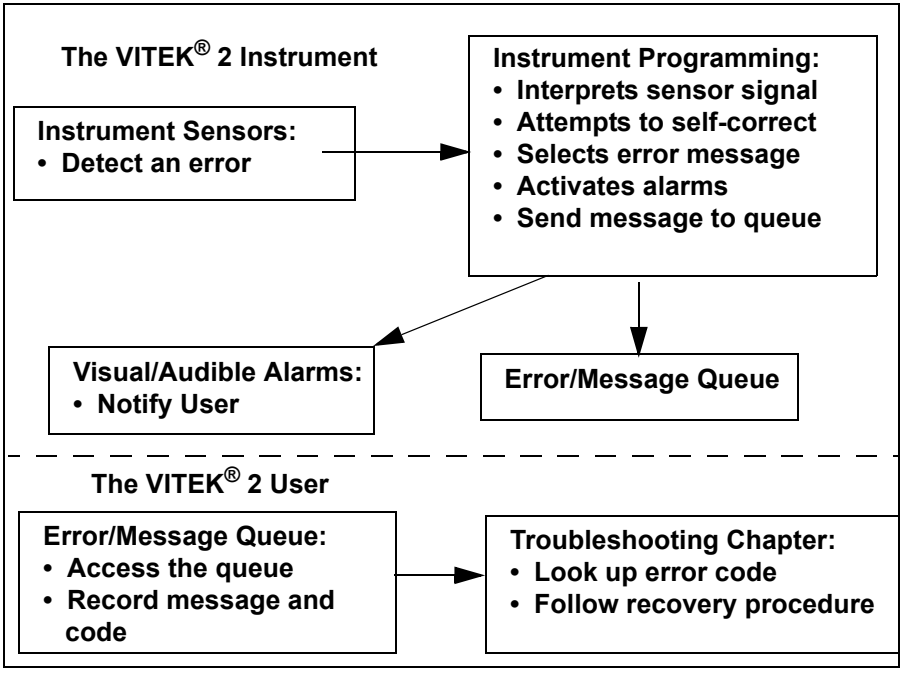

Figure 8-1: VITEK® 2 Error Handling System

The first element of the Error Handling System is the VITEK® 2 instrument. First it must detect the error. In many cases, the instrument will attempt to correct the problem by retrying an operation. If that fails, the instrument selects the appropriate error message, activates the error alarms, and places the message in the error/message queue.

The second element of the Error Handling System is you, the VITEK® 2 user. First, you must:

- Respond to the alarm by accessing the error/message queue on the instrument interface.
- Read and record all messages in the queue.

- Look up the error code from the message in this chapter and follow the recovery procedure.

Error Alarms

VITEK® 2 has two alarms to alert you to the presence of an error condition. The dual alarms are provided in case the VITEK® 2 instrument and the workstation are in different locations. When they are in close proximity, the audible alarm on the instrument can be disabled as a configuration option.

Audible Alarm. This alarm sounds both at the VITEK® 2 instrument, and at the workstation. Another instrument configuration option allows you to set the volume of the audible alarm.

Visual Alarm. This alarm uses the screen on the interface display. When the visual alarm is activated, the screen flashes to indicate the presence of an error condition. An instrument configuration option allows you to disable the visual alarm.

CAUTION: Do not disable both the audible and the visual alarms. Doing so eliminates all indicators of an error condition, which could result in the termination of tests in progress.

Types of Errors

There are three basic types of errors:

- Errors that cause the Reader or Card Transport system to halt.
- Minor errors, during which the Reader or Card Transport system continues.
- Errors that occur while loading a new cassette.

Note: *All errors/messages are logged in the Error Log whether or not they are resolved. The log is cleared when the instrument is turned off.*

Status Screen Error Conditions

Depending on the type of error, you will see one or more types of screens.

- **Instrument Halted Screen.** Indicates an error has caused the Reader or Card Transport system to halt.

- **Status screen with a status of Messages.** Indicates there are error messages that need to be reviewed. These are minor errors that do not cause the Reader or Card Transport to halt.

There are two ways you can handle a Status screen with a status of **Messages**.

- Review the message and resolve the condition as indicated in Table 8-2.
- Review the message and decide not to resolve the condition.

Note: *If the first error recovery procedure directs you to contact bioMérieux, do so immediately.*

- **Status screen with a status of Error** Indicates a message has been reviewed but not resolved, or the recovery procedure was not successful. This status can only be cleared by resolving the condition that caused the original error.

Instrument Halted Screen

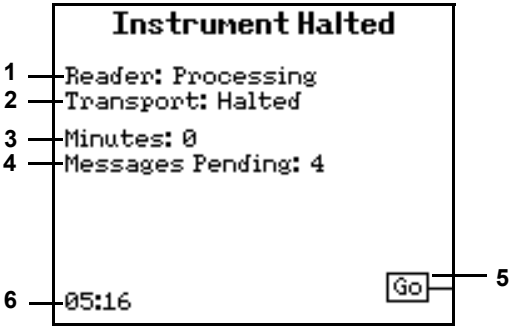

Figure 8-2: Instrument Halted Status Screen

1 – Reader. This field indicates whether the Reader Station is still processing, or has been halted due to the error.

2 – Card Transport. This field indicates whether the card transport system is still processing, or has been halted due to the error.

3 – Minutes. This field indicates how many minutes the error condition has existed.

4 – Message Pending. This field indicates how many messages are currently in the error/message queue. You can access the error/message queue by pressing the **Help (?)** key.

5 – Go Option Button. Press **Go** to resume processing after you have corrected the problem.

6 – 05:16. Time error occurred.

Reviewing an Instrument Halted Screen

1) Press **Help (?)** to view the error/message queue.

Note: *If there is more than one message, use the **Down Arrow** to review and address each message.*

2) Note the *error code number*, *primary error code*, and *secondary error code* listed on the error/message queue.

3) If the *secondary error code* listed is **Card Transport System Failure**, proceed to Resolving a Transport Halted Screen to resolve the error.

4) Look up the *primary error code* and then the *secondary error code* in Table 8-2 in this chapter. If an error recovery procedure is given, follow its directions, then continue with Step 5.

5) Press the **Previous Screen** key to exit the error/message queue and return to the Halted screen.

6) Press **Go** to resume processing.

- If the recovery procedure was successful, the Status screen appears with a Status of **OK**.
- If the Instrument Halted screen reappears, record the *error code number* and call bioMérieux.

Resolving a Transport Halted Screen

Note: *Only cards loaded into the jammed boat will be terminated. After the jam has been cleared, cards loaded into other non-jammed boats will continue to process and will be finalized when card processing is completed.*

1) Press the **Previous Screen** key to exit the error/message queue and return to the Halted screen.

2) Press **Go** to access the Transport Halted screen.

3) Open the front access door and the cassette load/unload door to check for any jams or obstructions throughout the transport system. Things to look for are:

- pipette tips that have fallen onto the base pan
- test cards that are not seated properly in the cassette
- boats that are not seated properly in their track

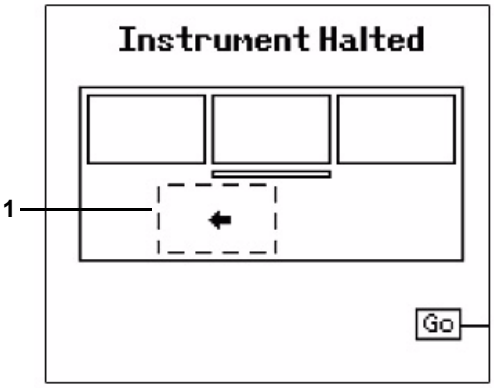

Figure 8-3: Transport Halted Screen (VITEK® 2)

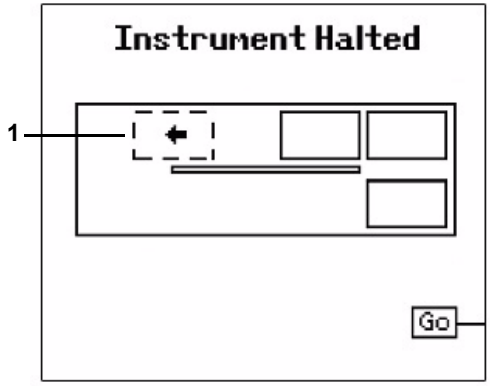

Figure 8-4: Transport Halted Screen (VITEK® 2 XL)

4) View the Transport Halted screen to find the jammed boat (**1**, Figure 8-3 or Figure 8-4).

Note: *Jammed boats are indicated by dotted line rectangles. Non-jammed boats are indicated by solid line rectangles.*

5) Move the jammed boat to the major base pan position indicated with the animated dotted lined rectangle and arrow on the Transport Halted screen.

Note: *An arrow inside the dotted line rectangle indicates the direction to move the jammed boat. The dotted line rectangle and arrow will animate from the jammed position to the new desired position.*

IMPORTANT: ***Jammed boats should only be moved as indicated on the Transport Halted screen. If a jammed boat is not moved to the location indicated by the animation on the Transport Halted screen, the instrument will***

indicate a Card Transport System Failure error again after the system has rebooted.

6) Close the front access door and the cassette load/unload door.

LASER WARNING

All access doors and covers must remain closed when processing cards to avoid exposure to laser light.

7) Press **Go** to exit the Transport Halted screen.

8) The instrument will make a clicking noise and automatically reboot.

- If the recovery procedure was successful, the Status screen appears with a Status of **OK** once the instrument has rebooted.
- If the Instrument Halted screen reappears, record the *error code number* and call bioMérieux.

Message Status Screen

This status indicates that there is an error message in the error/message queue that has not been viewed. Notice that the **Status** field (**1**, Figure 8-5) has changed to **Messages**, indicating that there are error messages in the error/message queue.

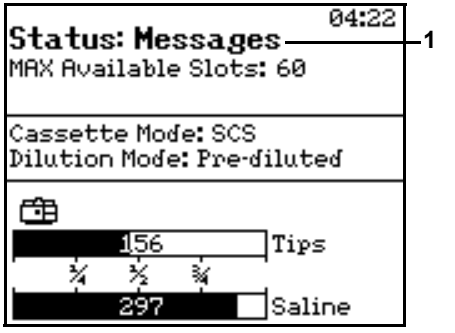

Figure 8-5: VITEK® 2 Status Screen

Press **Help (?)** to view the error/message queue.

If there is more than one message or error, press the **Down Arrow** to review and address each message.

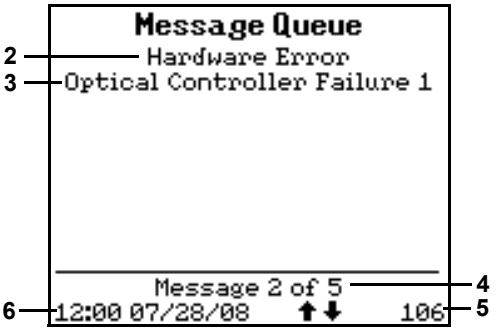

Figure 8-6: Message Queue

2 — Primary Error Code. The first line in the error/message queue gives you the Primary Error Code (in this case, Hardware Error). For examples of other Primary Error Codes, see Table 8-2.

3 — Secondary Error Code. The second line of the error/message queue tells you the Secondary Error Code (in this case, Optical Controller Failure). For examples of other Secondary Error Codes, see Table 8-2.

4 — Message Counter. The third line in the error/message queue is the message counter (in this case, 2 of 5). The counter tells you how many messages are in the queue.

5 — Error Code. The last line of the queue is the error code (in this case, 106). This code contains information for a bioMérieux service representative, should you need to call for assistance.

6 — 12:00. Time the error occurred.

Reviewing a Message Status Screen

1) Press **Help (?)** to view the error/message queue.

Note: *If there is more than one message, use the **Down Arrow** to review and address each message.*

2) Note the *error code number*, *primary error code*, and *secondary error code* listed on the error/message queue.

3) Look up the *primary error code* and then the *secondary error code* in Table 8-2. If an error recovery procedure is given, follow its directions, then continue with Step 4.

4) Press the **Previous Screen** key to exit the error/message queue and return to the Status screen.

- If the recovery procedure was successful, the Status screen appears with a Status of **OK**.
- If the Instrument Halted screen reappears, record the *error code number* and call bioMérieux.
- If a problem still exists, the word **Errors** will be displayed in the status field. The word **Messages** will display if a new message has been generated.

If a problem recurs, contact bioMérieux.

Error Status Screen

This status appears after the error/message queue is accessed if the error condition has not been resolved or the recovery procedure was not successful. This status can be cleared only by resolving the condition that generated the original message.

Review the error/message queue for any error messages the VITEK® 2 instrument has generated. Resolve the problem as indicated in Table 8-2.

Reviewing an Error Status Screen

When the status of **Messages** has changed to **Errors** this indicates one of two conditions:

- The message was reviewed but not resolved. Follow Step 1 through Step 4 in the procedure Reviewing a Message Status Screen on page 8-9.
- The recovery procedure was not successful. Call bioMérieux.

Cassette Load Processing Errors

Cassette load processing errors are a special set of errors that occur immediately following the loading of a cassette. You should be familiar with this type of error because:

- They are often caused by problems that can be resolved quickly, thereby preventing any interruption in your workflow.
- They occur at predictable times.

Types of Errors

During the first minute of processing, a cassette passes through the Bar Code and Button Memory stations. During this time the button memory of a smart cassette and the bar codes on all test cards are read. From this information, VITEK® 2 can detect the following errors:

- The bar code reader was unable to read one or more bar codes on the test cards.
- The card has passed its expiration date.
- An inconsistency was found between the information read from the button memory on the cassette and the bar codes on the test cards. For example, the button memory told VITEK® 2 that a Gram negative susceptibility card is in slot 4 of the cassette. The bar code reader, however, found that slot to be empty.
- (*Automatic dilution mode only.*) The bar code reader detected a susceptibility card for which there is no inoculum.
- The number of test cards in the cassette exceeds the number of available slots currently in the reader carousel.
- There is an insufficient quantity of pipette tips or saline to process the number of cards being loaded.

Workflow Considerations

For any type of load error, the VITEK® 2 instrument backs the cassette out to the Load Station so that you can resolve the error. If the cassette loading door is not opened within ***10 minutes***, the instrument assumes that no corrective action will be taken. The errors are ignored and the cassette is restarted. Any test card in the cassette that has a load error will not be processed. The cards remain in the cassette when the cassette returns to be unloaded.

Whenever you load a cassette, the cassette icon appears on the Status screen. You should wait until the icon disappears before leaving the instrument.

Bar Code Read Failure

As a cassette passes through the Bar Code Reader Station, the bar code on each test card is read. If the bar code reader is unable to read any of the bar codes:

- The cassette is backed out to the Cassette Load Station.
- The error alarm is activated.

Resolving Bar Code Read Errors

1) Press the **Help (?)** key to display the Error queue.

For a bar code error, you see the following message:

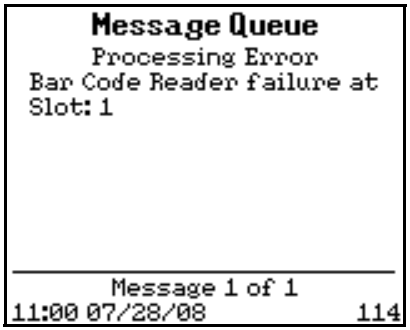

Figure 8-7: Bar Code Error Message

2) Open the door to the Cassette Load Station and remove the cassette. The door should remain open while resolving the bar code error.

BIOHAZARD WARNING

The cassette should be considered as potentially contaminated and should be handled appropriately. Qualified laboratory personnel should take the usual precautions necessary for infectious agents.

3) Remove the *card* from the slot indicated in the message.

4) Press the **Previous Screen** key twice to exit the error queue to the Main Menu.

5) Access the **Resolve Bar Code Errors** option on the Main Menu.

The Resolve Bar Code Error screen appears (Figure 8-8).

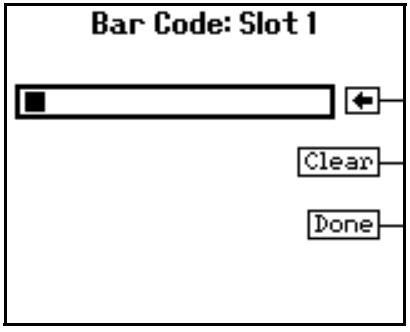

Figure 8-8: Resolving Bar Code Errors

6) Using the numeric keypad, enter the *bar code* from the bar code label. Press **Enter**.

Note: *The bar code you enter may be longer than the space provided on the screen. When this occurs, the first portion of the bar code scrolls off the display and the symbol > appears.*

7) VITEK® 2 checks your entry for:

- A valid bar code number.
- An expiration date.
- A card type match based on the bar code entered compared with the information read from the button memory on the cassette (Smart Carrier Mode only). See the following section for more information.

If there is another bad bar code, the screen in Step 5 reappears with the new slot number. Repeat Step 6. After the last bar code is entered, the display returns to the Main Menu.

8) Place the cassette back into the Cassette Load Station and close the door.

This restarts the processing cycle for this cassette.

SCS and Bar Code Reader Conflict

This type of error only occurs when VITEK® 2 is operating in Smart Carrier mode. That is because the error is based on a comparison of the information read from the bar codes with that read from the cassette memory. The card type is part of the information read on the bar code. Therefore, a card type error occurs if a test card type that is different from the one expected according to the cassette memory. If the instrument detects a card type error:

- The cassette is backed out to the Cassette Load Station.
- The error alarm is activated.

Resolving SCS and Bar Code Reader Conflicts

1) Press **Help (?)** to display the error/message queue.

For a card type error you see the following screen:

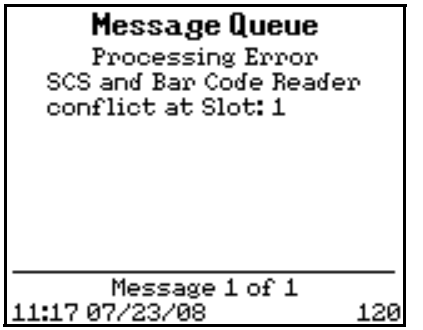

Figure 8-9: Card Type Error Message

2) Open the Cassette Load Station door, remove the cassette, and place it on the SCS.

BIOHAZARD WARNING

The cassette should be considered as potentially contaminated and should be handled appropriately. Qualified laboratory personnel should take the usual precautions necessary for infectious agents.

3) Press **F3** to display the Summary screen.

4) Check the positions and the types of test cards against the data displayed on the screen.

5) Move the test cards and their dilution tubes, as necessary, to match the data on the screen.

6) Place the cassette back in the Cassette Load Station and close the door.

This restarts the processing cycle for the cassette.

Inoculum Errors

When VITEK® 2 is operating in the Automatic Dilution mode, every susceptibility test card must be provided with an inoculum source. The inoculum must be placed in the slot that immediately precedes the susceptibility card. It can be placed next to an empty slot, or a slot containing a matching identification card.

Note: *For Gram negative test cards, the inoculum can be followed by one or two susceptibility cards.*

Note: *A matching identification card is one having the same accession ID and test type (gram +/gram -) as the susceptibility card.*

During the bar code read, the instrument checks for one of these two conditions. If the instrument detects an inoculum error:

- The cassette is backed out to the Cassette Load Station.
- The error alarm is activated.

Resolving an Inoculum Error

1) Press the **Error/Message** key to display the message queue.

For an inoculum source error you see the following screen:

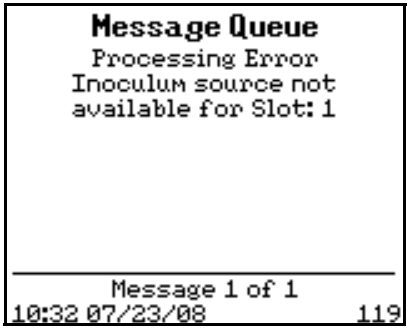

Figure 8-10: Inoculum Source Error Message

Note: *Another inoculum error message is "Grouping Error at Slot: NN".*

2) Open the Cassette Load door and remove the cassette.

BIOHAZARD WARNING

The cassette should be considered as potentially contaminated and should be handled appropriately. Qualified laboratory personnel should take the usual precautions necessary for infectious agents.

3) Place the inoculum source next to the appropriate slot.

4) Place the cassette back into the Cassette Load Station and close the door.

This restarts the processing cycle for the cassette.

Card Capacity Errors

As the bar codes on the test cards are read, the cards are counted. The count is compared to the number of empty slots currently available in the reader carousel. If the number of cards exceeds the number of available slots:

- The cassette is backed out to the Cassette Load Station.
- The error alarm is activated.

Resolving a Card Capacity Error

1) Press **Help (?)** to display the error/message queue.

For a card capacity error you see the following screen:

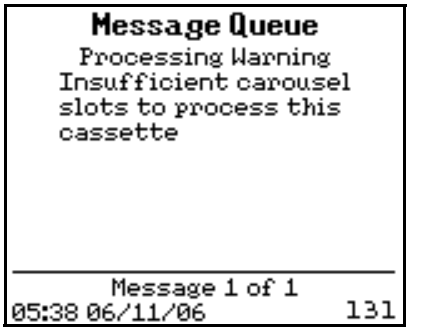

Figure 8-11: Card Capacity Warning Message

2) Open the Cassette Load door and remove the cassette.

You can remove a number of test cards from the cassette to resolve this type of error. However, there is another option available because it takes several minutes for a cassette to reach the Reader Station. During this time, additional carousel slots can be made available by ejecting cards whose tests have finalized. Continue the procedure as follows:

3) Consult the card directory at the workstation. Count the number of cards whose tests have finalized and that can be ejected.

4) Eject those cards using the workstation software.

5) If there are still too many test cards in the current cassette, remove the needed number of cards.

6) Place the cassette back into the Cassette Load/Unload Station and close the door.

This restarts the processing cycle for the cassette.

Note: *If the instrument's card capacity is exceeded, the extra test cards are not processed, and will be unusable.*

Disposables Errors

When a cassette begins processing, VITEK® 2 calculates the quantity of disposables that will be needed. If the calculated value exceeds the current level of a disposable:

- The cassette is backed out to the Cassette Load Station.
- The error alarm is activated.

How to Resolve a Disposables Error

1) Press the **Help (?)** key to display one of the following messages:

```
Tip Level Low or Saline Level Low
```

2) Open the Cassette Load door and remove the cassette.

3) Perform the procedure in Chapter 7 to install a new VITEK® 2 accessory kit and saline bag.

4) Place the cassette back into the Cassette Load Station and close the door.

Working Without the Bar Code Reader

A good reading of the test card bar code is required by the system to know the card type and how to process it. The primary method of entering these bar codes is the Bar Code Reader Station in the VITEK® 2 instrument. There are also two backup methods:

- The bar code scanner on a Smart Carrier Station, which is then transferred to VITEK® 2 via the smart cassette.
- Manually on the VITEK® 2 interface keypad.

If the Bar Code Reader Station fails, one of the two backup methods could be used.

Entering Bar Codes Manually

Failure of the Bar Code Reader Station on the VITEK® 2 instrument would result in a bar code read error for every card processed. This can be avoided by disabling the station, and then entering bar codes via the Smart Carrier Station, or manually on the VITEK® 2 keypad.

Disabling the Bar Code Reader

1) Access the **Bar Code Reader** configuration option using the path:

Main Menu > **Utilities** > **Configuration**

The Bar Code Reader screen appears:

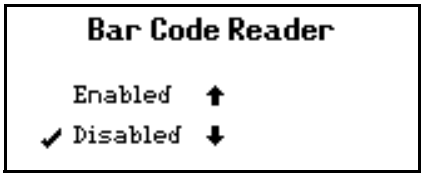

Figure 8-12: Bar Code Reader Screen

2) Press **Down Arrow** to disable the bar code reader.

Entering Bar Codes Manually

3) Access the **Resolve Bar Code Errors** option on the Main Menu.

4) Using the numeric keypad, enter the *bar code* from the bar code label.

5) Press **Enter** to accept the entry. Repeat this step for each test card in the cassette.

Note: *The bar code you enter may be longer than the space provided on the screen. When this occurs, the first portion of the bar code scrolls off the display and the symbol > appears.*

Note: *Press **Enter** to bypass empty slots.*

6) Press **Done** when all the cards have been entered for the Cassette.

Instrument Diagnostics

Some of the error recovery procedures in this chapter ask you to perform a diagnostic test on one of the stations in the VITEK® 2 instrument. This section tells you how to access and use those tests.

Instrument Diagnostics Menu

All of the diagnostic tests for the instrument are located on the **Diagnostics** menu, which can be accessed using the following path:

Main Menu > **Utilities** > **Diagnostics**

Diagnostic Tests

Following are the tests found on the **Diagnostics** menu, and their function:

Diagnostic Test	Function	Possible Results
Temperature	Reads the temperature in the reader carousel.	Displays the carousel temperature in degrees Celsius. Also displays the word **Low** or **High** if the temperature is out of specification.
Optics	Performs a self-test of the transmittance optics systems.	Pass/Fail
Card Transport	Performs a self-test of the Card Transport system.	Pass/Fail
Vacuum	Performs a vacuum test of the Filler station.	Pass/Fail
Dispenser/Pipettor	Performs a saline dispensing and a simulated organism suspension transfer.	Pass/Fail
Error/Message Log	Stores all errors/messages occurring since the power was last turned on. When you power off the VITEK® 2 all messages and errors are deleted from this log.	NA

Note: *Some of the diagnostic test functions contain a confirmation screen. These are included for the diagnostic tests that take several minutes to run. The confirmation window asks if you want to continue.*

Checking the Instrument Temperature

Access the **Temperature Diagnostics** using the path:

Main Menu > **Utilities** > **Diagnostics** > **Temperature**

If you have a VITEK® 2 XL, the screen in Figure 8-13 displays.

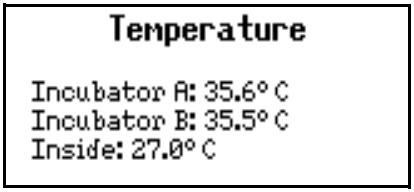

Figure 8-13: Temperature Diagnostics Screen (VITEK® 2 XL)

If you have a VITEK® 2, the screen in Figure 8-14 displays.

Figure 8-14: Temperature Diagnostics Screen (VITEK® 2)

The screen displays the Incubator temperature and the temperature inside the instrument.

Dispenser/Pipettor Diagnostic Test

Note: *The transport system must be idle to perform this test.*

This test is designed to be performed:

- after installing an Accessory Kit to confirm correct operation of the dispenser/Pipettor Station.
- during the error recovery procedure for a dispenser or Pipettor failure.

1) Prepare a *cassette* with the following items:

- Two test tubes containing 3.0 mL saline, placed in test tube slots 1 and 3.
- Three blank test tubes, placed into test tube slots 2, 4, and 5.

Note: *This cassette does NOT require the use of the Smart Carrier Station.*

2) Access the **Dispenser/Pipettor diagnostic test** using the path:

Main Menu > **Utilities** > **Diagnostics** > **Dispenser/Pipettor**

The following message displays:

```
About to perform dispenser Pipettor test. Do you wish
to continue?
```

3) Press **Yes**.

A message on the display will instruct you to load the cassette that you prepared in Step 1.

4) Open the Cassette Load door, load the cassette and close the Cassette Load door.

5) While the instrument is performing this test, open the front door of the instrument and visually check the saline dispenser for any of the abnormal conditions listed below.

- Look for repeated back and forth movement while the saline dispenser is in the upright position. The saline dispenser tube should move smoothly up and down when filling each AST tube.
- Look for saline remaining in the saline dispenser tube when it returns to the upright position.
- Look for a saline stream and/or drops released from the saline dispenser tube when it is filling with saline.
- Look for a saline stream and/or drops released from the saline dispenser tube as it returns to the upright position.
- Look for lower volumes of saline while saline is being dispensed, comparing tubes 2, 4 and 5 to each other.
- Observe the instrument user interface screen for Pipettor Failure 21 or any Dispenser Failures.

IMPORTANT: ***Ensure there is no sunlight shining directly on the saline dispenser.***

You can continue to use Automatic Dilution Mode if none of the abnormal conditions are observed.

If you see any of the above abnormal conditions or instrument errors continue to occur, please discontinue using Automatic Dilution Mode and contact bioMérieux immediately. You can configure the instrument to use the Predilution Mode as described in Chapter 5 of this manual.

Dispenser/Pipettor Volumetric Test

This test is not required by bioMérieux as part of the recommended routine maintenance procedures. This test has been provided for those laboratories who are required to verify the accuracy of the volumes dispensed by the Pipettor/Dispenser by regulatory/licensing agencies.

Note: *The transport system must be idle to perform this test.*

1) Prepare a *test cassette* with the following items:

- Two test tubes containing 3.0 mL saline, placed in test tube slots 1 and 3.
- Three blank test tubes, placed into test tube slots 2, 4, and 5.

Note: *This cassette does NOT require the use of the Smart Carrier Station.*

2) Record the *weights* of the test tubes placed in test tube slots 1, 3, and 5 using Table 8-1.

- Record the *weight* of the tube in slot 1 in the Pipettor Low Volume section. Test tube 1 — Before test (B).

- Record the *weight* of the tube in slot 3 in the Pipettor High Volume section. Test tube 3 — Before test (B).
- Record the *weight* of the tube in slot 5 in the Diluter section. Test tube 5 — Before test (B).

Use Table 8-1 to record the weights of your test tubes. Make one copy for your use and keep the original in this manual.

Table 8-1: Dispenser/Pipettor Volumetric Test

Pipettor Low Volume	Results	Date Tested	Performed By
Test tube 1 — Before test (B)			
Test tube 1 — After test (A)			
Weight of 1 (B) — 1(A) Acceptable range 0.095 g to 0.105 g			
Pipettor High Volume			
Test tube 3 — Before test (B)			
Test tube 3 — After test (A)			
Weight of 3 (B) — 3 (A) Acceptable range 0.285 g to 0.315 g			
Diluter			
Test tube 5 — Before test (B)			
Test tube 5 — After test (A)			
Weight of 5 (A) — 5 (B) Acceptable range 2.33 g to 2.63 g			

3) Access the **Dispenser/Pipettor diagnostic test** using the path:

Main Menu > **Utilities** > **Diagnostics** > **Dispenser/Pipettor**

The following message displays:

```
About to perform dispenser Pipettor test. Do you wish
to continue?
```

4) Press the **Yes** option button.

A message on the display will instruct you to load the cassette that you prepared in Step 1.

5) Open the cassette load door, load the test cassette and close the cassette load door.

6) Allow the cassette to process and return to the cassette load/unload door. Remove the cassette.

7) Record the weights of the test tubes placed in test tube slots 1, 3, and 5 using Table 8-1.

- Record the weight of the tube in slot 1 in the Pipettor Low Volume section under Test tube 1 — After test (A).
- Record the weight of the tube in slot 3 in the Pipettor High Volume section under Test tube 3 — After test (A).
- Record the weight of the tube in slot 5 in the Diluter section under Test tube 5 — After test (A).

8) Determine if the Dispenser/Pipettor is performing to specification by performing the following calculations using Table 8-1:

- In the Pipettor Low Volume section, subtract the weight of tube 1(A) from the weight of 1(B). The value must be 0.095 g and 0.105 g to be acceptable.
- In the Pipettor High Volume section, subtract the weight of tube 3(A) from the weight of tube 3(B). The value must be 0.285 g to 0.315 g to be acceptable.
- In the Diluter section, subtract the weight of tube 5(B) from the weight of tube 5(A). The value must be 2.33 g to 2.63 g to be acceptable.

Note: *If the values recorded in the tables are not within the recommended range, call bioMérieux for assistance.*

Cleaning Optics (Cards Processing)

This procedure allows you to clean and verify the optics while test cards are still processing. Use the optics cleaning procedure in Chapter 7 if the instrument is shut down.

Note: *All steps in this procedure must be completed.*

CAUTION: Do not wear powdered latex gloves while cleaning the optics. The gloves that contain a powder can interfere with the optics

CAUTION: Do not use commercial glass cleaner when cleaning the optics. This may result in calibration failures observed as the optics age. Clean optics using a quality, lint free lens paper that has been slightly moistened with alcohol.

1) Access the **Optics Cleaning** function using the path:

Main Menu > **Utilities** > **Maintenance** > **Cleaning** > **Optics Cleaning**

If cards are processing, the following message appears:

```
Cards are currently processing. Do you wish to
continue?
```

2) (*VITEK® 2 XL Only*) Select a *Reader*.

3) Press **Yes** to continue.

The screen briefly displays the message:

```
Preparing for Optics Cleaning.
```

You have five minutes from the time that you press **Yes** to complete the cleaning procedure. Test card processing automatically resumes after that time.

It then displays the following message:

```
Clean the optics.
```

4) Open the Waste Collection Station door and remove the test card collection tray. Dispose of any test cards in the tray.

5) Lift the top access door of the instrument.

This exposes the transmittance (**1**, Figure 8-15) optics.

This provides easier access to the optics and also an opportunity to clean this component.

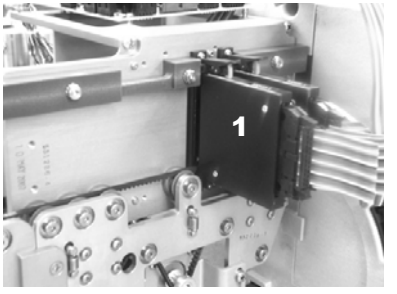

Figure 8-15: Optics

The optics consist of multiple units that are hinged on the bottom and held in place by spring-loaded levers.

Note: *Do each step for all transmittance optic units at the same time.*

6) Using your right hand, grasp the optics unit and place your thumb on the lever (**2**, Figure 8-16).

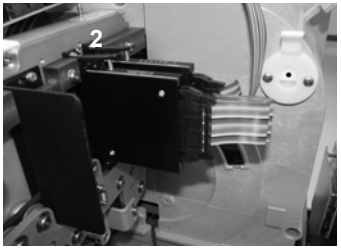

Figure 8-16: Opening the Optics

7) Push down on the lever to release the unit and allow it to rotate on its hinges.

8) Inspect the glass on both surfaces for cracks or scratches.

Note: Any apparent crack or scratch should be reported to bioMérieux.

9) Using a quality, lint free lens paper that has been slightly moistened with alcohol, clean both glass surfaces of each Transmittance Optics.

10) While cleaning the emitter side of the Transmittance Optics, push the reader head plate down and clean the glass as close to the belt as possible.

If foreign material remains on either surface, repeat this step using an alcohol wipe. Squeeze out excess alcohol before using, and dry the surface with lens paper. Make sure that you do not leave streaks on the glass.

11) Rotate the unit back into place while pushing down slightly on the lever until it is secured.

12) Replace the empty test card collection tray in the Waste Collection Station.

13) Close the top access door, then close the Waste Collection Station door.

14) Press **Cleaning completed**.

Note: *If Step 14 is not completed within the five minutes allowed, test card processing resumes automatically. If the optics are still open, the instrument generates an error condition.*

15) Continue with the Optical Diagnostic Test, noting the conditions of the test.

Optical Diagnostic Test

The Optical Diagnostic Test should not be performed if ID cards are processing. However, in some cases you need to perform the optical diagnostic test in response to an optics error.

- **Transmittance Optics Errors with ID Cards Processing —** After cleaning the transmittance optics in response to a transmittance optics error, await the next read cycle of the cards to determine if the cleaning was effective.
- **Transmittance Optics Errors without ID Cards Processing —** You may perform the Optical Diagnostic Test after cleaning transmittance optics in response to a transmittance optics error.

CAUTION: Performing the Optical Diagnostic Test while ID cards are processing may result in ID cards being TERMINATED.

1) Access the Optical Diagnostic Test using the path:

Main Menu > **Utilities** > **Diagnostics** > **Optics**

2) (*VITEK® 2 XL Only*) Select a *Reader*.

The following message appears for either the VITEK® 2 or VITEK® 2 XL:

```
About to perform optical test. Do you wish to
continue?
```

3) Press **Yes** to continue.

4) If the optical test fails, call bioMérieux.

5) Once the test is complete, press **Previous Screen** to exit the window.

Boat Transport Positions

The diagram below shows the six boat transport positions. During troubleshooting of jams involving the card transport system, it is important to know the boat positions inside the instrument. See Resolving a Transport

Halted Screen on page 8-6 for further information on card transport system jams.

LASER WARNING

All access doors and covers must remain closed when processing cards to avoid exposure to laser light.

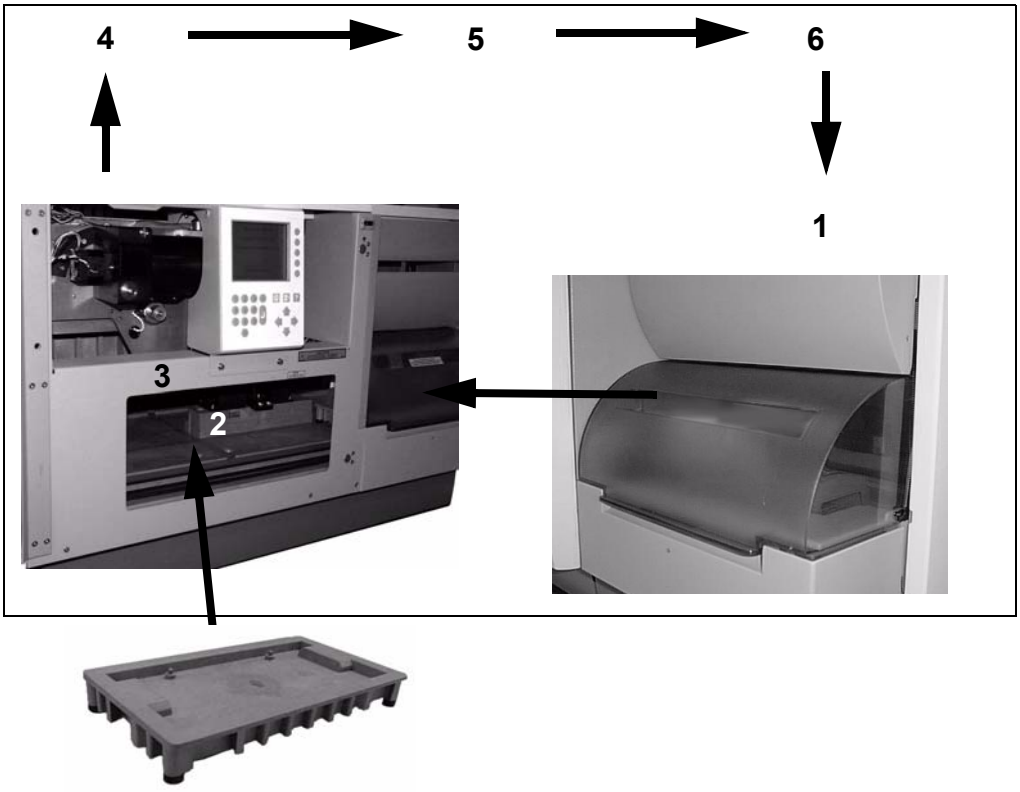

Figure 8-17: Boat Transport Positions

1 – Cassette Load/Unload Station. Boats must not be removed or replaced at this station.

This is the area you see when you open the front access door:

2 – Button Memory Station.

3 – Pipettor Station

When a boat is repositioned, center it on the opening between the two guide rails (see arrow in Figure 8-17) in the major base pan position indicated with

the animated dotted lined rectangle and arrow on the Transport Halted screen.

4 – Vacuum Station.

5 – Cut/Seal Station.

6 – Card Load/Unload Station.

Power Failures

What happens in the VITEK® 2 instrument if there is a power failure? The instrument is supported by a device called an Uninterruptible Power Supply (UPS). If power is lost, the UPS uses a battery to continue to supply power to the instrument.

The UPS notifies the VITEK® 2 instrument of a power failure. The following events then take place in the VITEK® 2 instrument:

- Initiates a Power Failure error message.
- Begins a 20-minute timer.
- Continues processing test cards in the carousel.
- Continues to support the card transport system, but does **NOT** allow new cassettes to be loaded.

If power is restored within the 20-minute period, normal operation is resumed. If the power failure continues after the 20-minute period has expired, VITEK® 2 shuts down the card transport system but continues to process cards in the carousel. Carousel processing continues as long as the battery in the UPS supplies power. If the backup battery in the UPS begins to fail before the 20-minute period expires, VITEK® 2 terminates the timer and shuts down the card transport system. Test cards, however, continue to process as long as any battery power is available.

Displaying Version Information

Allows you to view the current instrument firmware for the VITEK® 2. You may be requested to supply this information to bioMérieux if you need assistance with any of the recovery procedures in Table 8-2.

1) Access version information using the path:

Main Menu > **Utilities** > **Diagnostics** > **Version Info**

A screen displays similar to the one shown in Figure 8-18.

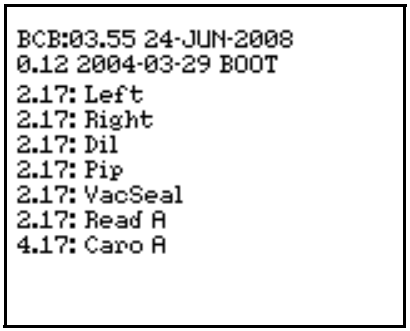

Figure 8-18: Version Information Screen

Using Error Message and Recovery Table

Table 8-2 in this section contains all of the messages that can be displayed in the error/message queue.

The Error Message and Recovery table is designed to provide you, where possible, with the recovery procedure that is most likely to restore the instrument to normal operation. If the described procedure does not prevent recurrences of the error, call bioMérieux for assistance.

1) Find the *primary error code* from the error message in the first column of the table. Primary error codes are listed alphabetically.

2) Find the *secondary error code* from the error message in the second column of the table.

3) Read and follow the directions in the Recovery Procedure found in the third column and address accordingly.

4) If the error reoccurs or the recovery procedure advises a call to bioMérieux, inform the service representative of the error number found in the lower right portion of the message queue.

Restarting the Instrument

Several of the recovery procedures in Table 8-2 instruct you to restart the instrument. To do this:

1) Perform the instrument shutdown procedure on page 7-25.

2) Wait at least 10 seconds.

3) Move the AC power switch to the ON position.

Table 8-2: Error Message and Recovery Table

Error Code		Recovery Procedure
Primary	**Secondary**	
Fatal Error	Call bioMérieux	Call bioMérieux for assistance.
Hardware Error	FLASH Memory Failure	Call bioMérieux for assistance.
	Incubator Temperature Controller Failure	Call bioMérieux for assistance.
	Internal Clock	Call bioMérieux for assistance.
	Internal Data Failure	Call bioMérieux for assistance.
	N/A	Call bioMérieux for assistance.
	Optical Controller Failure	***Note:*** *If the error code number listed is* ***406*** *or* ***407****, call bioMérieux for assistance. Do not perform the Cleaning Optics (Card Processing) procedure.* 1) See Cleaning Optics (Cards Processing) on page 8-23. 2) Call bioMérieux if the problem recurs.
	Serial Number Failure	Call bioMérieux for assistance.
Host Communication Error	Communication Failure	1) Ensure that the cable between VITEK® 2 to the workstation is connected securely. 2) Confirm that the workstation is operating. 3) If the error continues, call bioMérieux for assistance. ***Note:*** *If this error occurs while a software update is being performed, or during the automatic data backup, no action is required.*
	Card data has been lost	Call bioMérieux for assistance.

Table 8-2: Error Message and Recovery Table (Continued)

Error Code		Recovery Procedure
Primary	**Secondary**	
Initialization Error I	Card Sealer Failure	Call bioMérieux for assistance.
	Card Transport System Failure	Call bioMérieux for assistance.
	Dispenser Failure	Call bioMérieux for assistance.
	Incubator Temperature Controller Failure	Call bioMérieux for assistance.
	Internal Instrument Temperature Controller Failure	Call bioMérieux for assistance.
	Motor/Sensor Failure	Call bioMérieux for assistance.
	Pipettor Failure	Call bioMérieux for assistance.
	Power Fail Recovery Failure	Call bioMérieux for assistance.
	Transport Failure	Call bioMérieux for assistance.
	Vacuum System Failure	Call bioMérieux for assistance.
Optical Error	Optical Controller Failure	Call bioMérieux for assistance.
	• Transmittance Calibration Failure • Transmittance Process Failure	1) See Cleaning Optics (Cards Processing) on page 8-23. 2) Call bioMérieux if the problem recurs.
Processing Error	An optical system is not available for card type in slot.	1) Unload cassette from the instrument. 2) See Cleaning Optics (Cards Processing) on page 8-23 to clean and test the optics. 3) Reload cassette into the instrument. 4) If problem persists, call bioMérieux.
	Bar Code Read Failure at Slot	Follow the procedure for Bar Code Read Failure on page 8-11.
	Card has expired at Slot.	Replace the expired test card.
	Card Sealer Failure	Call bioMérieux for assistance.
	Card Transport System Failure	1) See Resolving a Transport Halted Screen on page 8-6. 2) Call bioMérieux if the problem recurs.

Table 8-2: Error Message and Recovery Table (Continued)

Error Code		Recovery Procedure
Primary	**Secondary**	
Processing Error (Cont.)	Carousel Jam	1) Open the waste collection door and top-right access door. 2) Remove the incubator access cover. (Refer to Step 5 of the procedure on page 7-12.) 3) Make sure that there is no card jammed between the reader head and the carousel. If there is, push the card into the carousel. 4) Make sure that there is no card jammed between the card loader and the carousel. If there is, push the card back into the cassette. 5) Install the incubator access cover. (Refer to Step 9 of the procedure on page 7-18.) 6) Close the top-right access and waste collection doors. 7) Press **Go** on the Halt screen. ***Note:*** *If the Halt screen is not displayed, press* ***Previous Screen*** *until it is.* 8) Call bioMérieux if the problem recurs.
	Cassette button memory failure	1) Unload the cassette from the instrument. 2) Confirm that the instrument is in Smart Carrier Mode. If the mode setting is correct, position the cassette back on the SCS and verify that it can read the cassette. 3) If SCS cannot read the cassette, clean the contacts on the button memory and place the cassette on the SCS. (See Step 4 in the procedures on page 7-20.) If still not successful, replace the button memory on the cassette and re-enter the data on the Smart Carrier Station. 4) If the SCS reads the cassette properly, squeeze out an alcohol wipe and then wipe the button memory contacts inside the VITEK® 2 instrument. Re-insert the cassette into the instrument. 5) If the problem recurs, call bioMérieux. ***Note:*** *If the instrument is in Cassette Only mode and this setting is correct, reload the cassette immediately and the cassette will process, ignoring information stored on the button memory.*

Table 8-2: Error Message and Recovery Table (Continued)

Error Code		Recovery Procedure
Primary	**Secondary**	
Processing Error (Cont.)	Dispenser Failure	1) Open the front access door and check for: • proper installation of the accessory kit. (See Accessory Kit installation procedure on page 7-4.) • a sufficient quantity of saline in the bag • tangles or pinches in the saline tubing 2) If needed, install a new accessory kit. 3) Perform the Dispenser/Pipettor diagnostic test. (See the procedure on page 8-20.) 4) If the problem continues, call bioMérieux. 5) If the problem recurs, call bioMérieux.
	General Failure	1) Press **Previous Screen** until either the Status screen or the Halt screen is displayed. 2) If the Status screen is displayed, empty the waste collection tray. (See page 6-32.) Also follow the procedure on page 8-23 to clean and test the optics. 3) If the Halt screen is displayed, open the waste collection door and top-right access door. 4) Remove the incubator access cover. (Refer to Step 5 of the procedure on page 7-12.) 5) Make sure that there is no card jammed between the reader head and the carousel. If there is, push the card into the carousel. 6) Make sure that there is no card jammed between the card loader and the carousel. If there is, push the card back into the cassette. 7) Install the incubator access cover. (Refer to Step 9 of the procedure on page 7-18.) 8) Close the top-right access and waste collection doors. 9) Press **Go** on the Halt screen. 10)Call bioMérieux if the problem recurs. ***Note:*** *If any cards terminate and remain in the carousel, wait for all cards to complete and then perform carousel cleaning. (See the procedure Removing the Carousel for Cleaning on page 7-10 and the procedure Replacing the Carousel After Cleaning on page 7-15.)*
	Grouping Error at Slot	The instrument has found a mated pair in which the test types do not match. Mated pairs require Gram negative ID and AST cards, or Gram positive ID and AST cards. Remove the cassette from the instrument and replace the appropriate test card.
	Inoculum source not available for Slot	Refer to the procedure for Inoculum Errors on page 8-14.

Table 8-2: Error Message and Recovery Table (Continued)

Error Code		Recovery Procedure
Primary	**Secondary**	
Processing Error (Cont.)	Load Failure	1) If the instrument has not displayed the Halt screen, go to Step 6 of this recovery procedure. 2) If the Halt screen is displayed, open the waste collection door and top-right access door. 3) Remove the incubator access cover. (Refer to Step 5 of the procedure on page 7-12.) 4) Check for a test card jam in the card loader (the mechanism near the bottom of the carousel that pushes test cards from the cassette into the carousel). Push any test cards that you find back into the carousel. 5) Press **Go** on the Halt screen. ***Note:*** *If test cards remain in the carousel, you can allow them to finish processing. You should not, however, load new cards into the instrument until after you have completed this recovery procedure.* 6) After all test cards have finished processing, remove the four carousel sections and remove any test cards that are found. (See the procedure Removing the Carousel for Cleaning on page 7-10, and the procedure Replacing the Carousel After Cleaning on page 7-15.) You cannot reprocess test cards after a Load Failure. Any test cards found in the carousel in Step 6 must be discarded. If the cards terminated immediately after loading, check for obstructions throughout the transport system and perform the Card Transport Test on page 8-19.
	Pipettor Failure	1) Open the front access door and check for the presence of pipette tips in the container. 2) If needed, install a new accessory kit. (See the procedure for adding pipette tips on page 7-8.) 3) Check for the presence of pipette tips that may have fallen onto the base pan, and remove them. 4) Perform the Dispenser/Pipettor diagnostic test. (See the procedure on page 8-20.) 5) If the problem continues, call bioMérieux.
	Process Jam	Refer to the Recovery Procedures for any messages that have approximately the same date/time stamp.
	Reader Error Occurred	Refer to the procedure on General Failure on page 8-33.
	SCS and Bar Code Reader conflict at Slot	Follow the procedure for SCS and Bar Code Reader Conflict on page 8-13.

Table 8-2: Error Message and Recovery Table (Continued)

Error Code		Recovery Procedure
Primary	**Secondary**	
Processing Error (Cont.)	SCS information has errors at Slot	1) Remove the cassette from VITEK® 2. 2) Put the cassette on the SCS. 3) Press **F10** to erase the data in the button memory. 4) Re-enter the data for the cassette.
	SCS memory contains old information that has previously been processed	1) Make sure that the VITEK® 2 instrument is in the correct cassette mode. (See procedure on page 5-5.) 2) If the problem still continues, call bioMérieux for assistance.
	Unknown Card Type at Slot	1) Make sure that the test card has been entered in the Flex Panel Entry screen at the workstation computer. 2) Try processing the test card again. 3) If the problem recurs, call bioMérieux for assistance.
	Unload Failure	1) Open the Waste Collection Station door and check for jams. 2) Empty the waste collection tray (See page 6-32). 3) Open the top-right access door. 4) Remove the incubator access cover. (Refer to Step 5 of the procedure on page 7-12.) 5) Make sure that there is no card jammed between the reader head and the carousel. If there is, push the card into the carousel. 6) Make sure that there is no card jammed between the card loader and the carousel. If there is, push the card back into the cassette. 7) Install the incubator access cover. (Refer to Step 9 of the procedure on page 7-18.) 8) Close the top-right access and waste collection doors. If the problem recurs, call bioMérieux for assistance.
	Vacuum System Failure	1) After all test cards have finished processing, clean the seal on the vacuum chamber and all surfaces of the boat. (See page 7-28.) 2) Perform the vacuum test on the Instrument Diagnostics menu. (See page 8-19.)
Processing Warning	Cannot unload cards, waste tray is full	Empty the test card waste collection tray. (See the procedure on page 6-32.)
	Cannot unload cards, waste tray is not available	Reinstall the test card waste collection tray. (See the procedure on page 6-32.)

Table 8-2: Error Message and Recovery Table (Continued)

Error Code		Recovery Procedure
Primary	**Secondary**	
Processing Warning (Cont.)	Cannot unload cards, waste tray is not functional	1) Open the Waste Collection Station door and check for jams. 2) Empty the waste collection tray. (See page 6-30). 3) Call bioMérieux for assistance if the problem recurs.
	Waste tray cannot hold the number of cards currently in the Carousel	Empty the test card waste collection tray. (See procedure on page 6-30; see also Waste Tray Warning Level on page 5-8.)
	No cards found	1) Unload the cassette from the instrument. 2) Check that the cassette contains a card. 3) Reload the cassette into the instrument.
	Cassette Loading door is open	Close the Cassette Load door. If the error recurs, call bioMérieux for assistance.
	Saline has been in use longer than the recommended time	The saline has been in the instrument longer than the specified time. Replace the saline bag. (See procedure on page 7-4.)
	Saline Level Low	Replace the saline bag. (See procedure on page 7-4.)
	Tip Level Low	See procedure on Disposables Errors on page 8-17.
	Tips have been in use longer than the recommended time	The pipette tips have been in the instrument longer than the specified time. Install a new Accessory Kit. (See procedure on page 7-8.)
	Incubator cover is off	Open the top-right access door and replace or reseat the incubator cover. (Refer to Step 9 of the procedure on page 7-18.)
	Incubator Temperature HIGH	Ensure that the ambient room temperature is below 30 °C. Wait 15 minutes and recheck. If the incubator temperature has not returned to normal, call bioMérieux for assistance. Test cards that are still processing in the carousel will be terminated after this error occurs. A laboratory report will be printed with the message: `CARD TERMINATED: Insufficient incubation time for analysis.` For AST cards, any antibiotics that were finalized prior to the error will be reported.

Table 8-2: Error Message and Recovery Table (Continued)

Error Code		Recovery Procedure
Primary	**Secondary**	
Processing Warning (Cont.)	Incubator Temperature LOW	Ensure that the ambient room temperature is above 20 °C. Wait 15 minutes and recheck. If the incubator temperature has not returned to normal, call bioMérieux for assistance. Test cards that are still processing in the carousel will be terminated after this error occurs. A laboratory report will be printed with the message: `CARD TERMINATED: Insufficient incubation time for analysis.` For AST cards, any antibiotics that were finalized prior to the error will be reported.
	Internal Instrument Temperature is HIGH	Ensure that the ambient room temperature is below 30 °C. Wait 15 minutes and recheck. If the instrument temperature has not returned to normal, call bioMérieux for assistance.
	Insufficient slots to process this cassette	Refer to procedures for Card Capacity Errors on page 8-16. You should check the Status screen before loading a cassette to make sure you have a sufficient number of slots available.
	Power Fail. System will park until power is restored	Normal processing will resume when power is restored. See page 8-28 for description of how instrument handles power failures.
	The Uninterruptible Power Supply has a Low Battery	Call bioMérieux for assistance if this error occurs when there is not a power failure. (This would be a normal error during a power failure.) See page 8-28 for description of how instrument handles power failures.
	Instrument status is cleaning	The instrument did not detect one of the carousel sections. Refer to Cleaning the Carousel on page 7-10.

APPENDIX A: HARDWARE SPECIFICATIONS A

VITEK® 2 Instrument

Dimensions

Dimension	VITEK® 2	VITEK® 2 XL
Height	67 cm (26.3 in.)	67 cm (26.3 in.)
Width	100 cm (39.4 in.)	140 cm (55.1 in.)
Depth	71 cm (27.7 in.)	71 cm (27.7 in.)

Mass

	VITEK® 2	VITEK® 2 XL
Mass	Approximately 110 kg (240 lb.)	Approximately 145 kg (320 lb.)

CAUTION: The VITEK® 2 instrument is heavy. Use at least two people to move it. Lift handles are provided at each end of the instrument.

Environment

Note: *The specifications below apply to both the VITEK® 2 and the VITEK® 2 XL.*

Indoor usage

Do not install in direct sunlight

Benchtop should be level within 2°

Minimum of 5 cm (2 in) clearance on all sides for adequate ventilation; 50 cm (20 in) above

Minimum installation altitude: –100m

Maximum installation altitude: 2000m

Ambient room temperature: 20 °C to 30 °C

Shipment and storage temperature: –20 °C to +50 °C

Relative humidity: 20% to 80% non-condensing

Pollution degree 2 in accordance with IEC 664

Overvoltage Category II per IEC 664

Electrical Characteristics

Electrical Characteristics	VITEK® 2	VITEK® 2 XL
Input voltage	200/240 VAC at 50/60 Hz 100/120 VAC at 50/60 Hz	200/240 VAC at 50/60 Hz 100/120 VAC at 50/60 Hz
Maximum input current	4 amps @ 120 VAC or 2 amps @ 240 VAC	5 amps @ 120VAC or 2.8 amps @ 240 VAC
Nominal input current	1.5 amps @ 120 VAC or 0.75 amps @ 240 VAC	2.75 amps @ 120 VAC or 1.75 amps @ 240 VAC
Power	150 watts nominal, 471 watts peak	200 watts nominal, 569 watts peak
Heat	512 BTU/HR (nominal)	682 BTU/HR (nominal)
Power cord	Detachable 3-wire with ground, per IEC 227 or IEC 245	Detachable 3-wire with ground, per IEC 227 or IEC 245

Optical Characteristics

Note: *The specifications below apply to both the VITEK® 2 and the VITEK® 2 XL.*

Transmittance Optics

Emission wavelengths: 660 nm, 568 nm, 428 nm LED

Percent transmission range: 30% to 100% ± 10%

General Characteristics

Note: *The specifications below apply to both the VITEK® 2 and the VITEK® 2 XL.*

Cassette

Capacity, cassettes: 4 cassettes maximum

Capacity, cards: 15 cards per cassette

Dispenser

Dispensing volume: 2.33 – 2.63 mL

Capacity: 1000 mL, user replaceable

Pipettor

Dispensing volume: 60 μL to 300 μL ± 5% or ± 5 μL, whichever is greater

Pipettor drum capacity: 330 pipette tips minimum, user replaceable

Vacuum (Filler)

Minimum level: 0.89 PSIA ± 0.06 PSIA

Sealer

Mechanical: stub length 0.025 mm to 2.5 mm

Incubator

Temperature: 35.5 °C ± 1 °C average

Capacity: 60 cards per Incubator

GLOSSARY

Access Doors VITEK® 2

VITEK® 2 has six doors to enable the operator to access the internal systems and stations to replenish supplies and perform maintenance and cleaning procedures: top access door, saline access door, front access door, bottom access door, cassette load (and unload) door, and waste collection access door.

Access Doors VITEK® 2 XL

VITEK® 2 XL has nine doors to enable the operator to access the internal systems and stations to replenish supplies and perform maintenance and cleaning procedures: top access door section A, top access door section B, saline access door, front access door, front center sliding door, bottom access door, cassette load (and unload) door, and 2 waste collection access doors.

Accession/Lab ID

The Accession ID is a unique identifier that associates a patient culture to a test card in the VITEK® 2 system. The Accession ID, which can contain up to 20 alphanumeric characters, is followed by a dash and a single-digit isolate number. Accession ID is the same as Lab ID.

Accessory Kit

Supplied by bioMérieux, the accessory kit contains the tubing, disk filter, and shot tube for the Dispenser station, and a container of pipette tubes.

Aliquot

A calculated unit of saline (see *Dispenser/Pipettor*) used with the organism culture to inoculate into the test card.

Antimicrobial Susceptibility Testing (AST)

Testing the susceptibility of certain bacteria to known antibiotic concentrations. VITEK® 2 helps the diagnostician determine the best medical treatment for the patient's specific strain of microorganism tested.

Analytical System

Located in a portion of the instrument called the Reader/Incubator station, it consists of the carousel, and two optics systems. The transmittance optics system indirectly measures organism growth as a function of decreasing light transmittance.

Automatic Dilution Mode

One of two possible settings for the Dilution Mode configuration on the VITEK® 2 instrument. In Automatic Dilution mode, AST suspensions are diluted by VITEK® 2. In Pre-diluted mode, the user prepares AST suspensions prior to loading test cards on the instrument.

Bar Code	An alphanumeric interface identifier label affixed to each VITEK® 2 test card. The bar code contains the card's test type, lot number, and expiration date, which is entered either by the SCS subsystem by bar code wanding, or when the test card's bar code label is read by the bar code reader inside of the VITEK® 2 instrument.
Boat	The tray-like device that carries the cassette around the instrument. It forms the bottom of the vacuum chamber and helps to capture any spills. It is removable for cleaning.
Button Memory	A Button Memory is a microchip located in a clip underneath the Cassette that stores test card information that is entered at the Smart Carrier Station. During the entry cycle of processing, the data is transferred to the workstation computer by the button memory reader.
Button Memory Reader	A magnetic data storage device that reads the button memory and sends data entered at the Smart Carrier Station to the VITEK® 2 workstation computer.
Cannula	A small tube located in the saline dispensing chamber that is inserted into the saline bag. Also known as the "bag spike".
Card Transport System	Moves the test cards among the stations within the VITEK® 2 instrument. It consists of the cassette tray, boat, cassette loading and unloading station, electromechanical arms, card ejectors, and the waste collector station.
Carousel	The rotating incubator section, which holds up to 60 test cards per incubator.
Cassette	The cassette is a card and test tube carrier that holds up to 15 tests. It is used for sample preparation and processing inside the instrument. It can contain a button memory chip that is used to transfer information from the Smart Carrier Station to the VITEK® 2 Workstation computer.
CPU	Central Processing Unit, the electronics of the personal computers and workstations.
Dispenser	Dispenses 2.5 mL of 0.45% saline into an empty susceptibility card test tube. This system includes a saline dispensing system, 1,000 mL bag of sterile saline and a "fixed volume" saline dispenser tube.

Dispenser/Pipettor	Transfers and mixes the appropriate inoculum volume predetermined by the test card bar code (60 µL to 300µL - see *Aliquot*) to adjacent susceptibility tubes. The system includes a container for pipette tips, a displacement pump, and various tip mechanisms.
Disposables	VITEK® 2 disposables are pipette tips, sterile saline, test cards, and inoculum tubes. Disposable supplies are biohazardous after use and must be discarded according to local laws regarding biohazardous material. They should not be recycled or disposed of with normal trash, etc.
Filler Station	This station inoculates all of the cards in a cassette with the suspension contained in their corresponding test tubes. It utilizes a vacuum chamber and air pump.
Incubator	The incubator contains a heater and a circulating fan used to incubate the cards during test. The temperature is monitored and controlled through the use of two remote precision thermistors monitored by a microprocessor holding the card at an average temperature of 35.5 °C.
Instrument Bar Code Reader	This station reads the bar code label on each VITEK® 2 test card within the first minute after the test cards are read, and transfers all of the test card bar code data to the VITEK® 2 Workstation computer.
Job Aid Card	A laminated card containing frequently used functions that can be used as a quick reference tool. There is one Job Aid Card for the Smart Carrier Station, and another for the VITEK® 2 Instrument.
LED	Light emitting diode, a light emitting device used in optical displays (and such consumer products as microwave ovens and digital clocks). Also see *Transmittance Optics*.
Pre-diluted Mode	One of two possible settings for the Dilution Mode configuration on the VITEK® 2 instrument. In Pre-diluted mode, the user prepares AST suspensions prior to loading test cards on the instrument. See *Automatic Dilution Mode*.
Saline Dispenser Tube	A “fixed volume” chamber used to measure and dispense 2.5 mL of saline into a susceptibility tube.
Sample Preparation Stations	This multi-function VITEK® 2 system consists of several stations: Bar Code Reader, Button Memory Reader, Dispenser/Pipettor, Filler, and Sealer.

SCS Base Unit	See *Smart Carrier Station (SCS)*.
Sealer Station	This station, a part of the Sample Preparation System, seals each test card by cutting and sealing its associated inoculum transfer tube with a hot wire.
Smart Carrier Station (SCS)	A laptop computer-like device used to aid in setting up the test and for entering test information. It consists of the base unit (computer) with LCD display, bar code scanner, and the keyboard (slides under base unit). The system is optional, and offers many productivity and security features for the user. It has user-configured modes for automatic dilution for matching ID and AST Test cards.
Test Card	A 3.5 by 2.25 in. (76.2 by 49.45 mm) cassette card with 64 growth wells for biological testing in the VITEK® 2 system. Each well contains an air-dried suspension of a biochemical or antimicrobial used to identify microorganisms or to test their susceptibility pattern.
Transmittance Optics	A combination of light-emitting diodes (emitters) and photodiodes used to read the growth results in the card wells.
User Interface (UI)	The portion of the VITEK® 2 system in which the user and the system's software interact. The system has three user interfaces: Workstation computer, consisting of a monitor, keyboard, and mouse. VITEK® 2 instrument, consisting of a keypad and screen. Smart Carrier Station, consisting of a keyboard and screen.
Waste Collection Station	Once testing is complete, cards are stacked in a tray for disposal.
Workstation Computer	The workstation computer is the primary processor used in calculating test results. The workstation can also be used as a means to interface the VITEK® 2 system with a central laboratory or hospital computer system. The workstation computer provides the user with the graphical interface used with the mouse pointing device and workstation monitor, and a text interface for the keyboard.

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